



























**Foundation for the National Institutes of Health (FNIH)  
Accelerating Medicines Partnership (AMP)  
Extended Executive Committee (EEC)  
Teleconference Meeting Minutes**

Friday, June 30, 2017  
7:00 – 8:30 a.m. ET

**Participants**

Salvatore Alesci (Takeda), Neil Buckholtz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Andrew Dahlem (Lilly), Mike Decker (AbbVie), Mikael Dolsten (Pfizer), Mark Erion (J&J), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Miletich (Merck), Gary Nabel (Sanofi), Dina Paltoo (NIH), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztejn (NIH/NIAMS), Phil Smith (NIH/NIDDK), Jim Sullivan (AbbVie), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

(b) (4), (b) (5)











**From:** Melencio, Cheryl (FNIH) [T] on behalf of Wholley, David (FNIH) [T]  
**Sent:** Wed, 28 Jun 2017 09:28:08 -0400  
**To:** Buckholtz, Neil (NIH/NIA) [C]; Canet-Aviles, Rosa (FNIH) [T]; Carter, Robert (NIH/NIAMS) [E]; Collins, Francis (NIH/OD) [E]; Decker, Mike; Dolsten, Mikael; Gadbois, Ellen (NIH/OD) [E]; Sheri Grabus; Hodes, Richard (NIH/NIA) [E]; Hodge, Martin; Hoffmann, Steve (FNIH) [T]; Katz, Stephen I. (NIH/NIAMS) [E]; tkerere@iqsolutions.com; Koroshetz, Walter (NIH/NINDS) [E]; Lea, Allison (NIH/OD) [E]; Lifton, Richard; Lundberg, Jan; Jennifer McCulley; Menetski, Joseph (FNIH) [T]; Paltoo, Dina (NIH/OD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Ryan, Laurie (NIH/NIA) [E]; Serrate-Sztejn, Susana (NIH/NIAMS) [E]; Smith, Philip (NIH/NIDDK) [E]; Stoffels, Paul; Sutherland, Margaret (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Terry, Sharon MA; Thomas, Melissa; Vardanian, Lilit (FNIH) [T]; Wholley, David (FNIH) [T]; Lon Cardon; Chin, Bill; Ehlers, Michael; Erion, Mark; Hait, Bill; Miletich, Joseph; Plump, Andrew; Sullivan, Jim; Woodcock, Janet (FDA/CDER); Zerhouni, Elias; thomas.lynch@bms.com; dahlem\_andrew\_m@lilly.com  
**Cc:** Alesci, Salvatore; Carrillo, Maria; Collins, Mary; Eakin, Guy; Fillit, Howard; Goldmuntz, Ellen (NIH/NIAID) [E]; Sheri Grabus; Hanrahan, Leslie; Hendrix, James; Lappin, Debra; List, James; Marchiolo, Eryn; Jennifer McCulley; Pragnell, Marlon; Rotrosen, Daniel (NIH/NIAID) [E]; Tarrant, Teresa; Vallance, Patrick  
**Subject:** MATERIALS for AMP Extended Executive Committee Teleconference June 30, 2017  
**Attachments:** AMP Extended EC 6-30-2017 FINAL.pptx, 2016\_12\_16\_AMP EEC teleconference draft (003) final clean.pdf, AMP functional validation proposal and responses 5-31-17.pdf  
**Importance:** Low

Dear AMP Extended Executive Committee members:

Attached are the materials for our call **from 7:00AM to 8:30AM Eastern U.S. Time this Friday, June 30:**

1. The PowerPoint slide deck that will be used to guide our discussions during the meeting
2. An Adobe .pdf document outlining a proposal by Lon Cardon and Patrick Vallance regarding how AMP might approach pre-competitive functional validation of targets, along with comments and responses from each of the three launched AMP research initiatives (AD, T2D, RA/SLE). As you may recall this proposal was originally suggested by Dr. Cardon on our last EEC call on December 16, 2016, and will be discussed further on this Friday's call.
3. An Adobe .pdf document containing the draft minutes from our December 16, 2016 AMP EEC call.

Call-in information is contained in the Microsoft Outlook calendar invitation you received for this meeting, but is repeated below. On behalf of the EEC co-chairs, Francis Collins and Mikael Dolsten, I look forward to an efficient and productive discussion.

### Join WebEx meeting

Meeting number: (b) (6)

Meeting password: (b) (6)

Join by phone



US/Canada: (b) (6); France: 0805 770 131; Germany: 0800 588 9700; UK: 0808 239 9879;  
Switzerland: 0800 661 155 Participant Code: (b) (6) Moderator Code: (b) (6) Project code: (b) (6)

Can't join the meeting?

Regards,  
David

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
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# Accelerating Medicines Partnership Extended Executive Committee Update #6

30 June 2017



NIH - 003



















# Accelerating Medicines PartnershipType 2 DiabetesPhil Smith, NIDDK

(b) (4)

(b) (4)



**FNIH**

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NIH - 003849



























# FNIH

NIH - 003860

























# Accelerating Medicines Partnership Alzheimer's Disease

Laurie Ryan, NIA

(b) (4)



NIH - 003871

























# Accelerating Medicines Partnership Parkinson's Disease Program Development Marg Sutherland, NINDS



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NIH - 003881











# Extended Executive Committee

- **Next Meeting:AMP Extended Executive Committee:  
December 15, 2017 from 7:00am – 8:30 am Eastern  
US Time**

**Foundation for the National Institutes of Health (FNIH)  
Accelerating Medicines Partnership (AMP)  
Extended Executive Committee (EEC)  
Teleconference Meeting Minutes**

Friday, December 16, 2016

8:00 – 9:30 a.m. EST

**Participants**

Salvatore Alesci (Takeda), Neil Buckholtz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Francis Cuss (Bristol-Myers Squibb), Michael Decker (Abbvie), Mikael Dolsten (Pfizer), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Marty Hodge (Pfizer), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Allison Lea (NIH), James List (Janssen), Jan Lundberg (Lilly), Joseph Miletich (Merck), Amanda Niskar (Arthritis Foundation), Griffin Rodgers (NIH/NIDDK), Laurie Ryan (NIH/NIA), Philip Smith (NIH/NIDDK), Nicole Spear (FNIH), Susana Serrate-Sztejn (NIH/NIAMS), Margaret Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Janet Woodcock (FDA), Frank Nestle (Sanofi), Philip Larson (Sanofi), Terry Tarrant (Rheumatology Research Foundation)

(b) (4), (b) (5)





























**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 01:47:13 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Carter, Robert (NIH/NIAMS) [E]; 'Hodge, Martin' (Martin.Hodge@pfizer.com); Hoffmann, Steve (FNIH) [T]; Smith, Philip (NIH/NIDDK) [E]; thomas, Melissa; Kamphaus, Tania (FNIH) [T]; Vardanian, Lilit (FNIH) [T]; Ryan, Laurie (NIH/NIA) [E]; collier\_david\_andrew@lilly.com; Canet-Aviles, Rosa (FNIH) [T]; Sutherland, Margaret (NIH/NINDS) [E]; Fischer, Stephanie (SFischer@phrma.org); Melencio, Cheryl (FNIH) [T]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]  
**Subject:** Materials for tomorrow AMP Extended Executive Committee pre-call  
**Attachments:** AMP Extended EC 12-15-2017 DRAFT.pptx, 2017\_06\_30\_AMP EEC teleconference final draft clean.docx, Copy of 15Dec2017\_AMP EEC Teleconference.xlsx

Francis, all,  
Please see the draft slide deck for tomorrow afternoon's pre-call and run-through of the AMP EEC call scheduled for 12/15. It includes the slidesets forwarded by the SC Co-chairs to date, minutes from the last EEC call in June, and list of respondents to date. I look forward to our conversation.  
Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

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# Accelerating Medicines Partnership Extended Executive Committee Update #7

15 December 2017



NIH - 003



















# Accelerating Medicines Partnership Type 2 Diabetes

Phil Smith, NIDDK

(b) (4)



NIH - 003

































# FNIH

NIH - 003922















































# Accelerating Medicines Partnership Alzheimer's Disease

Laurie Ryan, NIA



NIH - 003



































# Accelerating Medicines Partnership Parkinson's Disease Program Development (b) (4) (b) (4) Marg Sutherland, NINDS



**FNIH**

Foundation for the  
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NIH - 003958





























- **Next Meeting:AMP Extended Executive Committee:  
June 29**

# Backup Slides

**Foundation for the National Institutes of Health (FNIH)  
Accelerating Medicines Partnership (AMP)  
Extended Executive Committee (EEC)  
Teleconference Meeting Minutes**

Friday, June 30, 2017  
7:00 – 8:30 a.m. ET

**Participants**

Salvatore Alesci (Takeda), Neil Buckholz (NIH/NIA), Rosa Canet-Avilés (FNIH), Lon Cardon (GSK), Bob Carter (NIH/NIAMS), Francis Collins (NIH), Mary Collins (Lupus Research Alliance), Andrew Dahlem (Lilly), Mike Decker (AbbVie), Mikael Dolsten (Pfizer), Mark Erion (J&J), Ellen Goldmuntz (NIH/NIAID), James Hendrix (Alzheimer's Association), Richard Hodes (NIH/NIA), Steve Hoffmann (FNIH), Stephen Katz (NIH/NIAMS), Walter Koroshetz (NIH/NINDS), Joseph Miletich (Merck), Gary Nabel (Sanofi), Dina Paltoo (NIH), Griffin Rodgers (NIH/NIDDK), Daniel Rotrosen (NIH/NIAID), Laurie Ryan (NIH/NIA), Susana Serrate-Sztejn (NIH/NIAMS), Phil Smith (NIH/NIDDK), Jim Sullivan (AbbVie), Marg Sutherland (NIH/NINDS), Larry Tabak (NIH), Melissa Thomas (Lilly), Lilit Vardanian (FNIH), David Wholley (FNIH), Janet Woodcock (FDA)

(b) (4), (b) (5)













	A	B	C	D
1	December 15 AMP EEC			
2	Name	Attendance	Response	
3	Melencio, Cheryl (FNIH) [T]	Meeting Organizer	None	
4	Alesci, Salvatore	Required Attendee	Tentative	
5	Canet-Aviles, Rosa (FNIH) [T]	Required Attendee	Accepted	
6	Carrillo, Maria	Required Attendee	Accepted	
7	Carter, Robert (NIH/NIAMS) [E]	Required Attendee	Accepted	
8	Chin, Bill	Required Attendee	None	
9	Collier, David	Required Attendee	Accepted	
10	Collins, Francis (NIH/OD) [E]	Required Attendee	Accepted	
11	Collins, Mary	Required Attendee	Accepted	
12	Dolsten, Mikael	Required Attendee	Accepted	
13	Eakin, Guy	Required Attendee	Accepted	
14	Ehlers, Michael	Required Attendee	Accepted	
15	Erion, Mark	Required Attendee	Accepted	
16	Fillit, Howard	Required Attendee	Declined	alternate: Andrew Koemeter-Cox
17	Gadbois, Ellen (NIH/OD) [E]	Required Attendee	Accepted	
18	Goldmuntz, Ellen (NIH/NIAID) [E]	Required Attendee	Accepted	
19	Hait, Bill	Required Attendee	Declined	
20	Hanrahan, Leslie	Required Attendee	Accepted	
21	Hendrix, James	Required Attendee	Accepted	
22	Hodes, Richard (NIH/NIA) [E]	Required Attendee	Accepted	
23	Hodge, Martin	Required Attendee	Accepted	
24	Hoffmann, Steve (FNIH) [T]	Required Attendee	Accepted	
25	Kamphaus, Tania (FNIH) [T]	Required Attendee	Accepted	
26	Katz, Stephen I. (NIH/NIAMS) [E]	Required Attendee	Accepted	
27	Koroshetz, Walter (NIH/NINDS) [E]	Required Attendee	None	
28	Lappin, Debra	Required Attendee	Declined	
29	Lepore, John	Required Attendee	Accepted	Cardon's replacement
30	Lifton, Richard	Required Attendee	Accepted	
31	List, James	Required Attendee	Accepted	
32	Lundberg, Jan	Required Attendee	Accepted	
33	Lynch, Thomas	Required Attendee	Accepted	
34	Marchiolo, Eryn	Required Attendee	Accepted	
35	McCulley, Jennifer	Required Attendee	Accepted	

	A	B	C	D
36	Menetski, Joseph	Required Attendee	Accepted	
37	Miletich, Joseph	Required Attendee	Accepted	
38	Paltoo, Dina (NIH/OD) [E]	Required Attendee	Accepted	
39	Petanceska, Suzana (NIH/NIA) [E]	Required Attendee	Accepted	
40	Plump, Andrew	Required Attendee	Declined	sending alternate
41	Pragnell, Marlon	Required Attendee	Accepted	
42	Rodgers, Griffin (NIH/NIDDK) [E]	Required Attendee	Accepted	
43	Rotrosen, Daniel (NIH/NIAID) [E]	Required Attendee	Accepted	
44	Ryan, Laurie (NIH/NIA) [E]	Required Attendee	None	
45	Serrate-Sztein, Susana (NIH/NIAMS) [E]	Required Attendee	Accepted	
46	Singh, Jyoti (NIH/OD) [E]	Required Attendee	Accepted	
47	Smith, Philip (NIH/NIDDK) [E]	Required Attendee	Accepted	
48	Stoffels, Paul	Required Attendee	Accepted	
49	Sullivan, Jim	Required Attendee	Tentative	
50	Sutherland, Margaret (NIH/NINDS) [E]	Required Attendee	Accepted	
51	Tabak, Lawrence (NIH/OD) [E]	Required Attendee	Accepted	
52	Tarrant, Teresa	Required Attendee	Accepted	
53	Terry, Sharon	Required Attendee	Accepted	
54	Thomas, Melissa	Required Attendee	Accepted	
55	Vallance, Patrick	Required Attendee	Declined	
56	Vardanian, Lilit	Required Attendee	Accepted	
57	Wholley, David (FNIH) [T]	Required Attendee	Accepted	
58	Woodcock, Janet (FDA/CDER)	Required Attendee	Accepted	
59	Zerhouni, Elias	Required Attendee	None	
60	Science writer			
61	Grabus, Sheri	Required Attendee	Accepted	

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Nov 2017 20:28:02 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** Monday's AMP Extended EC Pre-Call

Francis:

We have a pre-call for the December 15 AMP Extended EC call on Monday December 4 from 2:30-3:30PM. So far it is just you and your team and my team. Since we are planning to run through the slide deck for the EEC, should we try to invite any of the co-chairs? We may not get all but would try for at least one from each of the 4 disease areas. Please let us know, thanks--David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 29 Jun 2017 15:18:23 -0400  
**To:** Collins, Francis (NIH/OD) [E];Dolsten, Mikael;Hodes, Richard (NIH/NIA) [E];Katz, Stephen I. (NIH/NIAMS) [E];Koroshetz, Walter (NIH/NINDS) [E];Lifton, Richard;Lundberg, Jan;Rodgers, Griffin (NIH/NIDDK) [E];Stoffels, Paul;Tabak, Lawrence (NIH/OD) [E];Terry, Sharon MA  
**Cc:** Boskent, Celeste (NIH/OD) [E];Bronson, Charlette (NIH/NIA) [E];Burrus-Shaw, Cyndi (NIH/OD) [E];Craver, Stephanie (NIH/NIAMS) [E];Doswell, Greta (NIH/OD) [E];Edmonds, Pamela;Yuliya Ilchik;McManus, Ayanna (NIH/OD) [E];Melencio, Cheryl (FNIH) [T];Meltzer, Sherry (NIH/NIAMS) [E];Poniente, Josefina;Poole, Charlene (NIH/NIDDK) [C];Protasiewicz, Ann;Walker, Paula (NIH/NINDS) [E];Wood, Gretchen (NIH/OD) [E];Zanellato, Ann;Canet-Aviles, Rosa (FNIH) [T];Gadbois, Ellen (NIH/OD) [E];Lea, Allison (NIH/OD) [E]  
**Subject:** Nomination for new industry Co-Chair for the AMP AD Steering Committee - ACTION REQUESTED  
**Attachments:** (b) (4), (b) (6) Biosketch\_2017.docx

Dear AMP Executive Committee Members:

As was discussed on our last AMP EC teleconference, Mike Decker of AbbVie will be stepping down as industry co-chair of the AMP Alzheimer's Disease Steering Committee within the next month.

(b) (4)  
(b) (4)

(b) (4)

Can you please let me know by return email to this address whether or not you approve appointment as AMP Alzheimer's Disease Steering Committee Co-Chair no later than Thursday, July 6? Your timely input would be most appreciated.

(b) (4), (b) (6)

Regards,  
David

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 5 Dec 2017 15:38:53 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** note for Janet

Francis—draft note you requested below

Hi Janet –

I am writing to check in with you about the Opioids Partnership in-person meeting that FNIH is holding on December 12-13 next week at the Bethesda Marriott. We did our best to find dates that would work, but inevitably conflicts arise, and one of these apparently is a meeting that FDA is holding on packaging and disposal standards for opioids on December 11 and 12. My understanding is that this could have affect FDA attendance on the 12<sup>th</sup> in particular, involving schedules of Sharon Hertz and Ellen Fields in particular. I think reasonably senior FDA involvement would be important to send the right signal to the public and to our industry partners in particular. In that light, would you be willing to be there on the 12<sup>th</sup>? If not, can you help identify someone suitable to represent FDA at this critical juncture in our efforts?

Regards,  
Francis

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 10 Oct 2017 01:04:14 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** FW: slides

Correcting email address

**David Wholley**  
**Director, Research Partnerships**  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, October 09, 2017 9:02 PM  
**To:** Volkow, Nora (NIH/NIDA) [E] (b) (6); Francis Collins (b) (6)  
**Cc:** Stein, Jack (NIH/NIDA) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** RE: slides

Nora, as you have seen from my previous emails I am supportive of the structure you recommend. My sense is that we at FNIH should attend meetings related to your sponsorship and organization of this effort (b) (5)

(b) (5) rather than the activities you have already been involved in, unless circumstances clearly indicate a PPP structure for your focus areas that clearly require focused FNIH project management and leadership. It would be good to delineate responsibilities here before the meetings with NAS Neuro Forum on Wednesday and Thursday, which Joe and Mike Biarnes from our staff plan to attend. We will do the right thing, whatever you and Francis decide—would appreciate definitive guidance from both of you on this.

David

**David Wholley**  
**Director, Research Partnerships**  
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**From:** Volkow, Nora (NIH/NIDA) [E]  
**Sent:** Monday, October 09, 2017 5:15 PM

**To:** Francis Collins (b) (6)  
**Cc:** Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>;  
Volkow, Nora (NIH/NIDA) [E] <nvolkow@nida.nih.gov>  
**Subject:** Re: slides

Dear Francis

(b) (5)

(b) (5)

(b) (5) Thaks, nora

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**From:** Jack Stein (b) (6)  
**Date:** Monday, October 9, 2017 at 8:10 AM  
**To:** Nora Volkow (b) (6)  
**Subject:** FW: slides

Nora -

Attached are 2 versions of the org structure for the PPP Rebecca generated and was discussed on Friday. It presents 2 versions of how things could work. FC was tending to the 2nd which has an overlapping advisory board (b) (5)

Below is David's email w assignments requested. (b) (5)

I am avail this afternoon or eve to call you if care to talk this thru.

Jack

From David -

Francis, as requested:

(b) (5)





David Wholley  
Director, Research Partnerships  
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Sent with BlackBerry Work  
([www.blackberry.com](http://www.blackberry.com))

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 21 Dec 2017 20:11:32 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Fw: Summary of the summit meeting  
**Attachments:** FNIH PPP Update for BMAC final draft 12-20-17.www.docx

Fyi I will look at this and send back to Rich in an hour or so unless I see something that could cause concern.

Sent from my BlackBerry 10 smartphone.

---

**From:** Moscicki, Richard <rmoscicki@phrma.org>  
**Sent:** Thursday, December 21, 2017 2:36 PM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** Summary of the summit meeting

Hi David, attached are some minor changes in the document. If you are ok with them, we will send to BMAC after legal review. Rich.















**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 21 Dec 2017 23:17:24 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** FW: Survey cover letter draft and remaining questions

Dear Francis and group:

As mentioned in Joe Menetski's note to Rebecca Baker below summarizing our call this morning with the Asset & Data Sharing Working Group co-chairs, several of the industry co-chairs in particular expressed concern about the length (as in number of rows) of the survey we'd be asking each company to fill out, even if prepopulated to some extent. One solution was to send the survey as an Excel worksheet with two tabs: A) one that includes rows for just the programs belonging to the particular company responding to the survey, which would be the primary information we would be seeking from them, and B) a second tab that contains all of the ~3000 or so rows in the current full worksheet, in case they have insights on other programs they wish to share. Several of the co-chairs briefly asserted that including opioids and NSAIDs in the list would be "useless" and provide a disincentive to companies to respond in areas that would be more fruitful for the collaborations we are seeking. The rest of the group seemed to agree broadly. There were no further specific comments as to sub-type or category of opioid or NSAID that should be excluded or more specific reasons for doing so. We repeated back to the group that what we should do is to leave opioids and NSAIDs in the general "TAB B" spreadsheet but exclude them from the company-specific "TAB A" section of the final survey, and the group confirmed that as their recommendation.

By the way this is not the first time we have heard this idea—the Asset Repurposing and Data Sharing Working Groups have asserted since the beginning of the process that there is an inverse relationship to the amount of data we seek in the survey and the prospect of getting a viable answer to our request from companies. There was even a brief discussion about this during the face to face meeting, though it apparently did not make it into the final discussion of key conclusions and action items. If there is indeed concern about removing opioids from TAB A of the survey, it might be useful middle ground if we can determine whether the concern is about removing any opioid program from TAB A or just some specific types of opioids.

Please let us know how you would like to handle as soon as possible.

Thanks, David

---

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Thursday, December 21, 2017 12:49 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>  
**Subject:** FW: Survey cover letter draft and remaining questions

Dear Rebecca,

Below are the results of today's discussion on the survey and the process for moving forward. David W has been read into this and can fill in any details that you may need to fill gaps.

Most of the meeting today was a discussion about writing assignments for the white paper, which will be provided by Michael B.

Best,

Joe

---

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Thursday, December 21, 2017 12:44 PM  
**To:** 'Flores, Christopher [CONUS]' <CFlores2@its.jnj.com>; 'Dunlop, John' <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6) Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** 'Osman.cigeroglu@pfizer.com' <Osman.cigeroglu@pfizer.com>; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>  
**Subject:** RE: Survey cover letter draft and remaining questions

Dear All,

Just recapping what I heard on the phone.

We will focus on getting the survey right, rather than getting it out prematurely in a unusable form.

To accomplish this, we will pilot the survey to several companies that are already involved in the partnership, but not currently involved in setting up the survey. Suggestions are; Pfizer, Lilly and Purdue. We will also send a survey to AZ, after John Dunlop has had a chance to contact an internal AZ acquaintance and prime them on the survey and the need.

Joe will generate excel files that contain tabs for 1) the entire list as it currently appears and 2) a company specific list that contains only programs from that request company. We will ask the company to update their programs in the company specific tab and also to provide any suggestions on programs that they are aware of in the full list.

We talked about removing the NSAIDs and opioids from the list, and I will remove them from the company specific list.

For the pilot, we should ask the partnership representatives to also provide their feedback on how the process of filling in the survey went (this may be best as a phone conversation).

Finally, I believe I heard that the pilot survey requests will be sent out after the first of the year. Suggested deadline of completion in 3 weeks after receipt of the survey.

Best regards,

Joe

---

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Thursday, December 21, 2017 9:09 AM  
**To:** 'Flores, Christopher [CONUS]' <CFlores2@its.jnj.com>; Dunlop, John <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>  
**Subject:** RE: Survey cover letter draft and remaining questions

Dear All,

Please find an updated version of the cover letter attached to this email. I have tried to incorporate your suggestion and comments. Please let me know if this sounds good enough to distribute widely?

Also, the asset repurposing co-chairs and Jack, have been added to the data sharing call today.

Along with a discussion on how we will get the white paper written, we will need to come to a resolution on how the survey is distributed. It is critical that this issue get resolved today.

We look forward to talking to you.

Best regards,

Joe

---

**From:** Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]  
**Sent:** Wednesday, December 20, 2017 6:48 PM  
**To:** Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Dunlop, John <jdunlop@amgen.com>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>  
**Subject:** RE: Survey cover letter draft and remaining questions

Dear all,

With thanks to Joe for drafting this cover letter and apologies for the delay in responding here – I've just finished unburying myself from being out last week☺ – please find attached my tracked suggestions on top of Michael's version. Admittedly, there is a needle to thread here in terms of balancing the desire for brevity with the need to provide compelling information.



Otherwise, I notice that not all of the co-chairs for the Data Sharing/Asset Repurposing workstream have been invited to tomorrow's TC; and so, may I please ask Cheryl to remedy this.

Looking forward to bringing this forward with all of you,  
Chris

---

**From:** Menetski, Joseph (FNIH) [T] [<mailto:jmenetski@fnih.org>]  
**Sent:** Wednesday, December 20, 2017 8:50 AM  
**To:** Dunlop, John <[jdunlop@amgen.com](mailto:jdunlop@amgen.com)>; Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Flores, Christopher [CONUS] <[CFlores2@its.jni.com](mailto:CFlores2@its.jni.com)>; Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** [Osman.cigeroglu@pfizer.com](mailto:Osman.cigeroglu@pfizer.com); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>  
**Subject:** RE: Survey cover letter draft and remaining questions

John, Michael, Chris and Chris,

Given the last 2 emails on this subject, I think it might be a good idea to have a short TC to settle the issue of how we send out the table. I don't want to be confusing, but I also don't want to make it so cumbersome that the results will be unmanageable when we get them back from the companies.

Would you be available for a 30 min meeting today or tomorrow?

I am open from 10-11am and after 1:30 today. My time is trickier tomorrow, but I will rearrange it to get together. I see that we have a co-chair meeting tomorrow with John and Michael, but I think this is an issue that we need to settle before that (also, I think the plan for that meeting is to discuss writing the white paper).

With respect to "unidentified pharmacological activity", you are absolutely right, it is problematic. On occasion, this can be obtained from detective work, but this is a field that the company responsible for the program should be able to identify easily, which would be the best solution. Otherwise, we will just have to remove them from deeper analysis. Generally this annotation is found in the preclinical space, but can sometime remain into later stages of development.

Please respond with you availability to talk, I can modify the table, but just need your decision on how.

Best regards,

Joe

---

**From:** Dunlop, John [<mailto:jdunlop@amgen.com>]  
**Sent:** Wednesday, December 20, 2017 8:33 AM  
**To:** Oshinsky, Michael (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; [cflores2@its.jni.com](mailto:cflores2@its.jni.com); Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** [Osman.cigeroglu@pfizer.com](mailto:Osman.cigeroglu@pfizer.com); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David

(FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>

**Subject:** RE: Survey cover letter draft and remaining questions

Joe

I'm afraid it has the opposite effect on me – too long and clunky. Maybe it's the way my brain is organized, or how it organizes things, but I'd prefer to see some additional formatting along the lines of separate tabs for pain-non-opioid, pain-opioid and addiction, e.g..

I also find 'unidentified pharmacological activity' to be problematic – in some cases there is a known pharmacology for the asset but its just not captured, while in other cases its truly not known – the latter is particularly problematic, requires additional level of detective work and low probability that there will be something behind that is exciting..

JD

---

**From:** Oshinsky, Michael (NIH/NINDS) [E] (b) (6)

**Sent:** Tuesday, December 19, 2017 1:25 PM

**To:** Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>; Dunlop, John <[jdunlop@amgen.com](mailto:jdunlop@amgen.com)>; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)

**Cc:** [Osman.cigeroglu@pfizer.com](mailto:Osman.cigeroglu@pfizer.com); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>

**Subject:** RE: Survey cover letter draft and remaining questions

Joe,

I have no problem with the length of the table, I think it's important to be inclusive of his many active and discontinued programs as possible.

Michael

---

Michael L. Oshinsky, Ph.D.  
Program Director, Pain and Migraine  
NINDS/NIH  
6001 Executive Blvd, Room (b) (6), MSC 9521  
Bethesda, MD 20892-9521  
Rockville, MD 20852 (for UPS, FedEx etc.)

Tel (b) (6)

FAX 301 402 2060

Email (b) (6)

---

**From:** Menetski, Joseph (FNIH) [T]

**Sent:** Tuesday, December 19, 2017 1:17 PM

**To:** Oshinsky, Michael (NIH/NINDS) [E] (b) (6); [jdunlop@amgen.com](mailto:jdunlop@amgen.com); cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)

**Cc:** [Osman.cigeroglu@pfizer.com](mailto:Osman.cigeroglu@pfizer.com); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>

**Subject:** RE: Survey cover letter draft and remaining questions

Thank you for the comments on the cover letter.

Could everyone please comment on the length of the table and excluding entries. We need to have that resolved before we send anything to a broader group.

Thank you,

Joe

---

**From:** Oshinsky, Michael (NIH/NINDS) [E]  
**Sent:** Tuesday, December 19, 2017 10:20 AM  
**To:** Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; jdunlop@amgen.com; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** RE: Survey cover letter draft and remaining questions

Joe,

Thank you for putting together this first draft. Here are my edits on the text for the email.

I would also like to suggest adding two fields to the contact information for a total of three fields. I am afraid that the field may be filled with a name only which is not as useful as the full contact information. The field will be: 1) contact name; 2) contact phone; 3) contact email.

Michael

---

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Tel (b) (6)

FAX 301 402 2060

Email (b) (6)

---

**From:** Menetski, Joseph (FNIH) [T]  
**Sent:** Tuesday, December 19, 2017 8:25 AM  
**To:** Oshinsky, Michael (NIH/NINDS) [E] <michael.oshinsky@nih.gov>; jdunlop@amgen.com; cflores2@its.jnj.com; Austin, Christopher (NIH/NCATS) [E] (b) (6)  
**Cc:** Osman.cigeroglu@pfizer.com; Stein, Jack (NIH/NIDA) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** Survey cover letter draft and remaining questions

Dear Asset and Data Sharing Co-chairs,

FNIH has put together a draft of a cover letter to request participation in filling in the survey. This is an initial draft, so please modify and comment so that we have the best chance of getting the information we need to be successful. I am providing the draft as a word document to allow changes to be tracked.

We have identified several issues that did not appear to be fully resolved at the face to face meeting. We need to make decisions on these before we distribute this survey request.

- We need to confirm that the columns included in the table are the right fields for the initial request.
- There was discussion that the initial prepopulated table should be reduced to only those programs that are likely to be of interest, or are only associated with companies currently in the development phase of the partnership. I do not remember (or have notes) that suggest we came to a definitive decision on this issue.

I have attached both the cover letter draft and the current survey to this email. We will not send out the survey until we have answers to the issues regarding the table and you have provided comments and modifications to the cover letter.

**We are on a very short timeline, so please respond by the end of business tomorrow, Wednesday the 20<sup>th</sup>, so we can get this out by the end of the week. If you think we need a short teleconference to discuss, let me know and I will put together a meeting.**

Best regards,

Joe

**We've moved! Please find our new address below.**

**Joseph P. Menetski, Ph.D.**

Deputy Director of Research Partnerships

**Foundation for the National Institutes of Health**

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[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda MD 20852

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 22 Dec 2017 18:18:37 +0000  
**To:** john.dunlop@amgen.com; Oshinsky, Michael (NIH/NINDS) [E]; Flores, Christopher [CONUS]; Colvis, Christine (NIH/NCATS) [E]  
**Cc:** Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** FW: Survey cover letter draft and remaining questions

Dear Asset & Data Sharing Co-Chairs:

We had an update call yesterday afternoon with Francis Collins, Nora Volkow, Walter Koroshetz and others to update them where things stand with the opioid partnership effort, including the survey. We mentioned that on yesterday morning's co-chair call with Joe Menetski and Mike Biarnes the suggestion was made by you all to remove opioids and NSAIDs from the individual program tabs we are asking the companies to look at as primary entries for the survey, in the interest of reducing as much as possible the amount of prepopulated rows the companies need to consider and improve POS. (I believe it was decided to leave this information in the second tab that lists all entries.)

This elicited a little concern from the group, particularly Nora, because while the value of opioids as analgesics may be lacking the feeling is they might have some relevance to opioid addiction or overdose reversal. This has in fact been discussed on some of the recent phone calls NIDA has been having with the Working Group addressing focused medications development. Would it be possible to find a way do you think to ask companies about broad categories of antagonists or diverse variety of agonists if the company feels they could be of particular value for addiction or overdose? I have copied Nora and some others here: please let us, and particularly Joe Menetski, know how we might best resolve this so we can send the survey out as soon as possible after the New Year—or, if you think it requires further discussion let us know and we can try to set up a brief conversation among the relevant individuals.

Thanks,  
David



**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 9 Mar 2017 16:31:27 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** FW: Update on AMP-PD proposal

Francis:  
Thank you, and fyi.  
David

---

**From:** [REDACTED] (b) (4), (b) (6)  
**Sent:** Thursday, March 09, 2017 1:50 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** Update on AMP-PD proposal

Hi, David –

(b) (4)



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 2 Oct 2017 18:07:42 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]  
**Subject:** FW: Update on PACT?

Hmm. Francis, I imagine we could give them until 5 pm on the 11<sup>th</sup> to make up their mind officially, as long as anyone they plan to have attend can be on alert and has the logistics info? Or Renate, am I dreaming here? Let me know please before I respond to Joanne.

Thanks, David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

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**From:** (b) (4)  
**Sent:** Monday, October 02, 2017 12:34 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** (b) (4); Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** RE: Update on PACT?

David,

(b) (4)

Best regards,

(b) (4)

---

**From:** Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]  
**Sent:** Monday, October 02, 2017 9:45 AM  
**To:** Lager, Joanne /US  
**Cc:** (b) (4); Adam, Stacey (FNIH) [T]  
**Subject:** RE: Update on PACT?

(b) (4)

Can you please give me an update on where this stands? NIH is moving forward with their communications and announcement plan for the 12<sup>th</sup>, and are asking me for status.

Thanks,  
David

David Wholley  
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**From:** (b) (4)  
**Sent:** Wednesday, September 27, 2017 3:28 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Cc:** (b) (4) Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>  
**Subject:** RE: Update on PACT?

David,

(b) (4)

---

**From:** Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]  
**Sent:** Tuesday, September 26, 2017 4:20 PM  
**To:** (b) (4)  
**Cc:** Adam, Stacey (FNIH) [T]  
**Subject:** RE: Update on PACT?

(b) (4)

The announcement of the launch of the Partnership to Advance Cancer Therapies (PACT) is almost certainly going to be on October 12, at the National Press Club. (b) (4)

Thanks, David

David Wholley  
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Foundation for the National Institutes of Health  
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---

**From:** [REDACTED] (b) (4)  
**Sent:** Monday, September 18, 2017 5:49 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** [REDACTED] Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** Re: Update on PACT?

David,

Sorry for the delayed reply. [REDACTED] (b) (6)

We are still in the process of [REDACTED] (b) (4) I will see if I can get a more definitive answer this week.

Best regards,  
[REDACTED] (b) (4)

Sent from my iPhone

On Sep 15, 2017, at 2:47 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

[REDACTED] (b) (4)  
[REDACTED] (b) (4) we are trying to confirm direction from the last couple of interested companies.

Please let me know, or any additional information I can supply you.

Best regards,  
David Wholley

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
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---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, September 08, 2017 10:21 AM  
**To:** [REDACTED] (b) (4)  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** Update on PACT?

[REDACTED] (b) (4)  
[REDACTED] (b) (4) Thank you,  
David Wholley

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 3 Nov 2017 15:50:02 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** PACT EC

Hi Francis –

Back to PACT for a moment. Stacey Adam and I met with Jim Doroshow and his NCI team last night to start getting set for the face to face meeting we are holding on November 16 to finalize the detailed research plan for PACT (as we did with the AMP initiatives). Among the topics tackled was governance, and NCI is working on suggested representatives for the JSC.

(b) (4)

Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

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[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 10 Mar 2017 16:19:47 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** PACT meeting follow-up

Hi Francis—

As I recall you had originally said you wanted to set up our PACT progress updates with Doug Lowy and Jim Doroshow to run about once a month. I just wanted to note that our last meeting was January 31, and I have not yet seen anything on the calendar about another one. Did you want to keep doing these? And if so, given that HEVER is April 7-9, would you want to set the next call a couple of weeks beforehand (the week of March 20 or the week of March 27, say) so we make sure we have time to discuss and prep materials you and Jim may need at HEVER? Just a thought.

David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 29 Sep 2017 13:04:02 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** PACT partners

Jay,

Great to see you last night, as always. To follow up your question, the companies that have committed to PACT (b) (4) are AbbVie, BMS, Boehringer-Ingelheim, Celgene, Genentech, GSK, Janssen, and Pfizer. (b) (4)

(b) (4)

Regards,  
Francis



**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 23 Jun 2017 18:10:29 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** PACT update: (b) (4)

As agreed I am forwarding updates on our outreach efforts for PACT as they occur.

(b) (4)

Thanks,  
David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
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[fnih.org](http://fnih.org)

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 6 Jan 2017 13:49:34 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Lea, Allison (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]  
**Subject:** PACT\_Update\_010617.pptx  
**Attachments:** PACT\_Update\_010617.pptx  
**Importance:** High

Francis – here are some slides to help facilitate our discussion at 2:15. I am sending them here to everyone who was on the formal invitee list our office received. Could your staff please forward them to anyone else who you want on the call? Thanks!  
David

# PACT Design Update

January 6, 2017



**FNIH**

Foundation for the  
National Institutes of Health

THE BOSTON CONSULTING GROUP

NIH - 004018



# PACT Design Working Group Members

<b><u>INDUSTRY PARTICIPANTS</u></b>	<b>Axel Hoos (GSK) – Industry Co-Chair</b>		<b>Jeff Engelman (Novartis) – Industry Co-Chair</b>	
	Andrew Schade (Lilly)	David Reese (Amgen)	Greg Plowman (Lilly)	Ute Dugan (BMS)
	Jessie English (EMD)	Vicki Goodman (BMS)	Armin Schuler (EMD)	Howard Fingert (Takeda)
	Paul Rejto (Pfizer)	Jeff Ecsedy (Takeda)	Bob Abraham (Pfizer)	Stuart Lutzker (Genentech)
	Flavio Solca (B-I)	Jianda Yuan (Merck)	Norbert Kraut (B-I)	Thomas J Hudson (AbbVie)
	Matthew Albert (Genentech)	Carl Barrett (Astrazeneca)	Chandra Ramanathan (Bayer)	Olaf Christensen (EMD)
	<b><u>GOVERNMENT PARTICIPANTS</u></b>	<b>Helen Chen (NCI-CTEP) – NIH Co-Chair</b>		<b>Percy Ivy (NCI-CTEP) – NIH Co-Chair</b>
Magdalena Thurin (NCI-CTEP)		Tony Kerlavage (NCI-CBIIT)	Lisa McShane (NCI)	Larry Rubinstein (NCI)
Howard Streicher (NCI-CTEP)		Kevin Howcroft (NCI-DCB)	Malcolm Smith (NCI)	Gideon Blumenthal (FDA-CBER)
Marc Theoret (FDA-CDRH)		Reena Phillip (FDA-CDRH)	Ke Liu (FDA-CBER)	Allison Lea (NIH-OSP)
Rebecca Baker (NIH-OD)				
<b><u>ACADEMIC PARTICIPANTS</u></b>	Mario Sznol (Yale)	Antoni Ribas (UCLA)	Patricia LoRusso (Yale)	Lillian Siu (PMCC)
	Jedd Wolchok (MSKCC)	Steve Hodi (DFCI)	Antoni Ribas (UCLA)	Charles Sawyers (MSKCC)
	Levi Garraway (Broad/Lilly)		John Byrd (OSU)	
<b><u>PACT PROGRAM MANAGEMENT</u></b>	David Wholley (FNIH)			
	Stacey Adam (FNIH)			















**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 3 Oct 2017 14:10:17 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Partnership to Accelerate Cancer Therapies  
**Attachments:** Updated PACT Executive Summary 092617.docx

Dear (b) (5).

It has been a while since we spoke about this, but I wanted to ask you for a favor regarding another public-private partnership we have been developing: the Partnership to Accelerate Cancer Therapies (PACT). As you might recall, we've spent the last 15 months or so working with FNIH, FDA, and multiple pharmaceutical companies to plan a partnership that would help coordinate the development of standardized biomarkers and assays needed to conduct trials of new cancer immunotherapies and combination therapies. The resulting plan builds on a \$160 million investment by NCI over 5 years in core laboratory and database infrastructure with (b) (5) to expand the number of novel markers, assays, and types of data that can be developed.

(b) (5)

The driving factor is that FNIH now has 8-9 companies pledged to support PACT, and that with encouragement from the White House we have committed to hold an announcement at the National Press Club downtown on October 12 (modeled on the announcements held for the Biomarkers Consortium and AMP). (b) (5)

(b) (5)

I have attached a 2-page summary of PACT for reference, but please let me know if you have any additional questions.

Warm regards, Francis

<Updated PACT Executive Summary 092617.docx>

## Executive Summary

Recent advances in cancer treatment have offered the prospect of greatly enhanced outcomes, prolonged survival, and cure for some patients. Much of the recent success has been driven by the development of new immuno-oncology (IO) agents, leading to an explosion of translational research as well as investment in the field. To date, however, the improvements in outcomes and cure generated by the monotherapies of these agents are possible only for a minority of patients, and emerging data demonstrate that the greatest impact on cancer treatment will be achieved by combinations of multiple IO agents or of IO and non-IO agents. The successful pursuit of these combination therapies is complicated, however, by the sheer numbers of possible combinations, by high biologic complexity, and by the need for new translational biomarkers and assays to guide which patients should receive which combinations. These challenges are further compounded by the novelty and intensely competitive nature of the IO field, which has encouraged fragmented and at times duplicative research approaches.

To solve these challenges, a systematic cross-sector effort is required to identify and develop robust, standardized biomarkers and related clinical data that support the selection and testing of promising therapeutic combinations. The magnitude of this task and the substantial current knowledge gaps within the field make it unlikely a single stakeholder can execute such a mission alone. As a part of its support of the Cancer Moonshot, the National Institutes of Health (NIH) has proposed a 5-year, ~\$210 million precompetitive public-private research collaboration called the Partnership for Accelerating Cancer Therapies (PACT) to enable achievement of these goals. The initial strategic plan for PACT has been developed through a process led by the Foundation for the NIH (FNIH) with input from 42 key opinion leaders in the cancer field, encompassing representatives from the National Cancer Institute (NCI), U.S. Food and Drug Administration (FDA), academia, and 15 industry partners—AbbVie, Amgen, AstraZeneca, Bayer, Boehringer-Ingelheim, BMS, EMD Serono, Genentech, GSK, Lilly, Merck, Novartis, Pfizer, PhRMA, and Takeda.

PACT aims to accelerate the development of effective combination therapies by enabling critical clinical investigations not covered by others, coordinating development of new biomarkers, filling knowledge gaps, and integrating information from multiple sources.

PACT will facilitate robust, systematic, and uniformly conducted clinical testing of basic biomarkers that enable researchers and clinicians to better understand the mechanisms of response and resistance to treatment strategies. PACT will provide a systematic approach to immune and related oncology biomarker investigation in clinical trials by providing standardized biomarker modules, which can be utilized within the PACT programs and across the research community. These modules allow for (a) consistent generation of data, (b) access to uniform and harmonized assays to support data reproducibility, (c) comparability of data across trials, and (d) discovery/validation of new biomarkers for combination immunotherapies and related combinations. Specific elements of the program include the following:

- Providing a set of basic biomarker modules for uniform clinical application.
- Establishing a network of 3–5 core laboratories to coordinate, conduct, validate, and standardize biomarker assays. Funding the development of standardized biomarkers for immunoprofiling and exploratory biomarker assays of high relevance.
- Incorporating biomarkers and data collection standards into trials prioritized through PACT and coordinating their adoption broadly across the IO research community.
- Creating a comprehensive database that integrates biomarker and clinical data to enable pre-competitive correlative biomarker analyses.

PACT will also work to provide scientific coordination by facilitating information sharing by all stakeholders to better coordinate clinical/translational oncology programs, align investigative approaches, avoid duplication of effort, share resources, and enable more relevant high-quality trials to be conducted. This will include active outreach to other IO research efforts on an ongoing basis.

The core laboratory, assay development, and database functions required will be built on a solid base of research infrastructure and academic grants funded by NCI. Fortuitously, NCI released several Requests for Applications (RFAs) in November 2016 that are highly germane to the core goals of PACT. Based largely on existing funding from the Precision Oncology Initiative, with additional planned Cancer Moonshot funding, the NCI plans to contribute ~\$160 million in funding over 5 years beginning in Fall 2017 for a number of Cancer Immune Monitoring and Analysis Centers (CIMACs), a Cancer Immunologic Data Commons (CIDC), and several related initiatives that create integrated multidisciplinary research cores with basic, translational, and computational expertise. Although currently limited as to the number of sites, assays, and data types supported, these grants provide a “shovel ready” foundation for the core lab and database functions required by PACT, particularly when combined with NCI’s recently announced Formulary initiative and its existing national clinical trials network and genomic data management programs.

In addition to supporting these resources, PACT will coordinate and standardize the use of existing biomarker assays so that they can be used efficiently in clinical trials of new medicines. These assays can be conducted in trials outside PACT yet channel data into the PACT database, provided the assays are performed to PACT standards.

(b) (4)

A joint governance structure will maintain close involvement by all partners in key decisions, consisting of:

- An operationally focused PACT Joint Steering Committee (JSC) to direct the research plan and ensure adherence to project milestones
- A PACT Executive Committee (EC) to provide strategic direction, communication with partner leadership, and resolution of policy issues.

Voting participation in the JSC and EC will be split 50/50 between government and private sector partners.

All PACT data will be released publicly as promptly and broadly as possible in keeping with NIH's mission and policy, though also dependent on restrictions in underlying clinical trial and grant agreements. Where feasible, PACT participants will have early access to data, but consistent with these restrictions.

The value proposition for PACT stakeholders, for the oncology field, and for patients will be considerable, providing immediate:

- Access to standardized immune biomarker modules, enabling a systematic and uniform analytical approach across trials
- Access to databases of pre-competitive biomarker analyses, accelerating hypothesis testing and decision-making
- Access to core development laboratories and facilities with standardized analysis platforms, procedures, and best practices, working with regulatory agencies to ensure quality evidence and documentation that enable potential registration and labeling
- Opportunity to drive new collaborations resulting from PACT insights and contribute to improving cure rates for patients under the goals of the Cancer Moonshot Initiative

(b) (4)

(b) (4) With confirmed partners, FNIH will reconvene the scientific leads to develop a final research plan, including detailed project plans and go/no-go milestones. Given the sense of urgency in addressing patient needs, the timing of NIH funding, and the rapid pace of progress in the field, formal launch of PACT is being targeted for Q1 of 2018.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 17 Mar 2017 08:51:42 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Jan Lundberg; Dolsten, Mikael  
**Cc:** Tabak, Lawrence (NIH/OD) [E]  
**Subject:** Re: [EXTERNAL] Further thoughts on replacing Francis Cuss on the AMP Executive Committee

Yes that sounds like a good next step. Thank you, Francis.  
Sent from my BlackBerry 10 smartphone.

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, March 17, 2017 7:21 AM  
**To:** Jan Lundberg; Wholley, David (FNIH) [T]; Dolsten, Mikael  
**Cc:** Tabak, Lawrence (NIH/OD) [E]  
**Subject:** RE: [EXTERNAL] Further thoughts on replacing Francis Cuss on the AMP Executive Committee

(b) (4), (b) (5)

Francis

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**From:** Jan Lundberg [mailto:lundberg\_jan@lilly.com]  
**Sent:** Friday, March 17, 2017 6:01 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Dolsten, Mikael <mikael.dolsten@pfizer.com>  
**Subject:** Re: [EXTERNAL] Further thoughts on replacing Francis Cuss on the AMP Executive Committee

(b) (4), (b) (5)

Best  
Jan

Sent from my iPhone

On Mar 16, 2017, at 8:14 PM, Wholley, David (FNIH) [T] <dwholley@fnihi.org> wrote:

Dear Francis, Larry, Jan, and Mikael:

As you know, Francis Cuss has stepped down from BMS as CSO and has been replaced by (b) (4), (b) (6). In advance of HEVER we are trying to come to some agreement about whom we might approach to replace him on the AMP EC, and in what priority. Thank you for the input you have provided thus far. (b) (4), (b) (5)

(b) (4), (b) (5)



As a next step, could I ask that you weigh in (perhaps by ranking them in your preferred order and adding any comments you may have) and copy the others on this email? Responses are of course confidential among this group. This should help us arrive at a rough consensus. Thank you for taking the time to share your thoughts.

David Wholley



**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 16 Mar 2017 10:22:49 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: 2016\_12\_16\_AMP EEC teleconference draft (003) final clean

Thanks Francis. Would you like me to copy Larry Tabak and Griff, Richard, and Steve on the first email or the second one?

Sent from my BlackBerry 10 smartphone.

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, March 16, 2017 5:16 AM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** RE: 2016\_12\_16\_AMP EEC teleconference draft (003) final clean

Hi David,

(b) (5)

FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, March 15, 2017 10:30 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: 2016\_12\_16\_AMP EEC teleconference draft (003) final clean

Hi Francis, just received this from Lon, as follow up to the EEC call on December 16. How would you like this to be handled? Our next EC call is not until May 5. Finding a common date to meet before then would be, as you know, a challenge, though we certainly could try. One solution could be that I send this out to the EC and the SC co-chairs and ask for them to send comments. We'd be asking the EC members for general comments on feasibility and preference on how to proceed; the SC co-chairs would hopefully provide some perspective on how these might be applied in their respective disease area. I would collate comments, and you, Mikael, and Jan could then take this with you to HEVER for further discussion. Please let me know how you'd like to proceed. Thanks, David

---

**From:** Lon Cardon [mailto:[lon.r.cardon@gsk.com](mailto:lon.r.cardon@gsk.com)]  
**Sent:** Tuesday, March 14, 2017 10:02 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>  
**Cc:** Patrick Vallance <[patrick.5.vallance@gsk.com](mailto:patrick.5.vallance@gsk.com)>  
**Subject:** RE: 2016\_12\_16\_AMP EEC teleconference draft (003) final clean

Hi David,

Just following up on the prompt below. Patrick Vallance and I have drafted a brief summary to initiate the conversation. It is attached.

Kind regards,  
Lon

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**From:** Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]  
**Sent:** Tuesday, February 21, 2017 4:53 PM  
**To:** Lon Cardon  
**Subject:** 2016\_12\_16\_AMP EEC teleconference draft (003) final clean

Dear Lon—

(b) (5)

(b) (5) I was reminded

of this on a call with Francis today and wanted to reach out to ask if you would be able to write something up fairly soon, as the EC will only have one or at most two more meetings before the Extended EC gets back together. I have attached the meeting minutes from the Dec. 16 call, with your comment highlighted in yellow, for convenience in recalling the context. Please let me know if you think this will be possible sometime in the next couple of weeks—appreciate you are likely extremely busy.

Regards,  
David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 23:37:40 +0000  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** RE: Additional Thoughts

I think both of these require careful consideration. (b) (5)

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, November 7, 2017 6:07 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** Additional Thoughts

All, I think our call was a good one. Two other thoughts. One, regarding communications, we might also consider the wisdom of a more public interim disclosure about our initial work in planning for the PPP. It would be a chance for the biopharmaceutical industry to indicate its support by virtue of the large representation of companies eager to help with the planning. Two, interactions with FDA. The more I think about the PPP, the more the criticality of early and continued conversations with the FDA becomes clear. (b) (5)

(b) (5)

(b) (5) Bill

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 7 Apr 2017 12:56:35 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: AMP EC Call Reschedule Update

Cheryl worked with what Gretchen gave her. But OK, I will ask Cheryl to go back to Gretchen and search forward to June if necessary.

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, April 07, 2017 12:23 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: AMP EC Call Reschedule Update

Hmm. How far forward did you search for dates? I'd really like to have full participation in the next EC call, especially because it will be Paul's first one. (I will try to give him some info this weekend at Hever.)

If we had to wait until June, but got full participation, that would be worth it.

FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, April 07, 2017 10:51 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: AMP EC Call Reschedule Update

Hi Francis, sorry to bother you, but we are still having trouble getting everyone together for the next AMP EC. Gretchen and Cheryl have worked on searching multiple dates, but the only one that seems to align with you and at least two of the other participants is May 12 at 7am. (And you will need to take that call from an airport I understand). The one who cannot make it is Jan Lundberg, but to be fair to Jan he could make a couple of other dates that neither Mikael Dolsten nor Paul Stoffels could make. Can you let me know how you'd like to proceed?  
Thanks, David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 29 Jun 2017 11:24:14 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Stoffels, Paul [JJCUS]  
**Cc:** Ray, Amrit [JJCUS]; Zanelato, Ann [JJCUS]  
**Subject:** RE: AMP EC tomorrow

Thanks for letting us know, Paul. I show Mark Erion as attending from Janssen.

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, June 29, 2017 6:02 AM  
**To:** Stoffels, Paul [JJCUS] <PStoffe4@its.jnj.com>; Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Ray, Amrit [JJCUS] <ARay@ITS.JNJ.com>; Zanelato, Ann [JJCUS] <AZanell2@its.jnj.com>  
**Subject:** RE: AMP EC tomorrow

Thanks for letting us know, Paul – we'll miss your participation but understand your schedule must be pretty daunting. David will follow up with any actions that come up during the call.

Best, Francis

---

**From:** Stoffels, Paul [JJCUS] [<mailto:PStoffe4@its.jnj.com>]  
**Sent:** Thursday, June 29, 2017 4:29 AM  
**To:** Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Ray, Amrit [JJCUS] <ARay@ITS.JNJ.com>; Zanelato, Ann [JJCUS] <AZanell2@its.jnj.com>  
**Subject:** AMP EC tomorrow

Dear Francis,

I wanted to let you know that tomorrow, I will not be able to participate in the AMP EC meeting. I'm chairing a one day meeting on "transforming clinical trials and regulatory pathways" including pharmaceutical industry RD leaders, senior leaders from FDA – EMA, as well as academic participation.

This as a follow up to the April Hever meeting key topic selection for IMI.

I will catch up on a later date. Best regards,

Paul





**From:** Wholley, David (FNIH) [T]  
**Sent:** Sat, 25 Mar 2017 12:15:20 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** RE: AMP Executive Committee Telecon

Yes, with this change we'll try another date. Hopefully this will prompt an answer from Paul as well.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, March 24, 2017 5:46 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** McManus, Ayanna (NIH/OD) [E] (b) (6)  
**Subject:** RE: AMP Executive Committee Telecon

Well, this time we might want to shift the date. (b) (6)

Can you work with my schedule (ccing Ayanna) to find a date that also works for Mikael, Jan, and (hopefully) our new guy Paul?

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, March 24, 2017 3:43 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: AMP Executive Committee Telecon

Ugh, again.

---

**From:** Melencio, Cheryl (FNIH) [T]  
**Sent:** Friday, March 24, 2017 3:16 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** FW: AMP Executive Committee Telecon

I just got this from Pam – for the May 5 AMP Call

-----Original Appointment-----

**From:** Pamela J Edmonds [[mailto:edmonds\\_pamela\\_j@lilly.com](mailto:edmonds_pamela_j@lilly.com)] **On Behalf Of** Jan Lundberg

**Sent:** Friday, March 24, 2017 3:14 PM

**To:** Melencio, Cheryl (FNIH) [T]

**Subject:** Declined: AMP Executive Committee Telecon

**When:** Friday, May 05, 2017 7:00 AM-8:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** (b) (6) France: 0805 770 131 Participant Code: (b) (6) Moderator Code:

(b) (6) Project Code: (b) (6)

Hi Cheryl, (b) (6) unavailable to participate. Thanks, Pam



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 16:41:59 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** note to Janet Woodcock

Francis, you asked me to remind you to reach out to Janet today regarding FDA attendance at the face to face opioids partnership meeting on December 12-13, since we have not heard back definitively from Sharon Hertz about who will attend on those dates. As a heads up/reminder: 1) FDA has had a representative on 7 of the 9 Working Group calls we have had to date, which is pretty good 2) the main issue is December 12, when FDA has its own meeting on safe packaging for opioids 3) Sharon did say she'd find someone, it just can't be her or Ellen Fields or Doug Throckmorton, and has not said who yet. Therefore, I would probably soft shoe this a bit with Janet rather than complain we don't have anyone—you understand there is an important meeting that day, FDA challenged to find people to come on the 12<sup>th</sup>, perhaps Janet would like to attend herself since you will be there... etc.

Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 20 Dec 2017 00:37:50 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** Opioid PPP update for BMAC 12-19-17 draft for NIH  
**Attachments:** Opioid PPP update for BMAC 12-19-17 draft for NIH.docx

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David







**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 21 Dec 2017 00:08:27 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** Opioid PPP update for BMAC 12-19-17 integrated clean  
**Attachments:** Opioid PPP update for BMAC 12-19-17 integrated clean.docx

Francis, please see the attached clean final draft of the opioids section of the update on FNIH partnerships requested by the BMAC. It has been reviewed by Larry, Nora, Walter, and Rebecca and I think captures the gist of our meeting and decision process to date. Please let me know any recommended changes as soon as possible so I can send to PhRMA. Thanks, David









**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 20 Dec 2017 21:10:15 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Subject:** Opioid PPP update for BMAC 12-19-17 integrated  
**Attachments:** Opioid PPP update for BMAC 12-19-17 integrated.docx

Thanks so much for integrating all the comments Rebecca. Attached are my answers to Larry's questions. I think his and Nora's suggested changes are good. David









**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 5 Dec 2017 18:34:41 +0000  
**To:** Collins, Francis (NIH/OD) [E];Tabak, Lawrence (NIH/OD) [E];Volkow, Nora (NIH/NIDA) [E];Stein, Jack (NIH/NIDA) [E];Koroshetz, Walter (NIH/NINDS) [E];Porter, Linda (NIH/NINDS) [E];Wolinetz, Carrie (NIH/OD) [E];Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T];Menetski, Joseph (FNIH) [T];Melencio, Cheryl (FNIH) [T]  
**Subject:** Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017  
**Attachments:** Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017.docx

All – here is the latest version of the Agenda for next week’s face to face meeting, incorporating the changes we discussed last Thursday. We did just add 15 minutes for me to go over the agenda and introduce Francis at the very start. Please let us know if you have specific changes or comments—this is the version we will use with the co-chairs on our call Thursday unless we hear different. Thanks, David



## **Partnership to Address the Opioid Crisis Face-to-Face Meeting**

Bethesda North Marriott Hotel – 5701 Marinelli Road, Rockville, MD 20852

**Tuesday December 12<sup>th</sup> – 7:30 AM – 6:30 PM**

**Wednesday December 13<sup>th</sup> – 7:30 AM – 4:00 PM**

### **Agenda**

#### **December 12<sup>th</sup>**

##### **WEBEX TO BE ADDED**

Meeting number (access code):

Meeting password:

- |                            |   |
|----------------------------|---|
| <b>7:30 am – 8:00 am</b>   | Registration and Breakfast  |
| <b>8:00 am – 8:15 am</b>   | Agenda Overview, Meeting Logistics<br><i>David Wholley (FNIH)</i>   |
| <b>8:15 am – 8:30 am</b>   | Welcome and Introduction<br><i>Francis Collins (NIH)</i>  |
| <b>8:30 am – 8:45 am</b>   | Overview of Focus Area A<br><i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i>   |
| <b>8:45 am – 9:00 am</b>   | Overview of Focus Area B<br><i>Walter Koroshetz (NINDS) [David Wholley (FNIH)]</i>  |
| <b>9:00 am – 12:30 pm</b>  | Focus Area A: OUD Treatment and Overdose Prevention/Reversal<br><i>Co-Chairs: Christopher Flores (J &amp; J Consumer); Osman Cigeroglu (Pfizer)</i> |
| <b>9:00 am – 10:00 am</b>  | New Formulations/Combinations of Existing OUD Medications<br><i>TBD</i>   |
| <b>10:00 am – 10:15 am</b> | Break   |
| <b>10:15 am – 11:15 am</b> | More Potent/Longer-lasting Antagonists to Reverse Overdose<br><i>TBD</i>  |
| <b>11:15 am – 12:15 pm</b> | Alternative Endpoints for OUD Medications<br><i>TBD</i>   |





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**Wednesday December 13<sup>th</sup> – 7:30 AM – 4:00 PM**

### **Agenda**

**12:15 pm – 12:30 pm** Focus Area A: Next Steps and Timelines for White Paper Development  
*TBD*

**12:30 pm – 1:00 pm** Lunch

**1:00 pm – 5:30 pm** Focus Area B: Development of New Pain Medications Working Groups

**1:00 pm – 3:00 pm** Asset Repurposing Working Group  
*Co-Chairs – Chris Austin (NCATS), Chris Flores (Johnson & Johnson)*

**3:00 pm – 3:15 pm** Break

**3:15 pm – 5:15 pm** Clinical Trials Network Working Group  
*Co-Chairs - Linda Porter (NINDS), Kenneth Verburg (Pfizer), Clinton Wright (NINDS)*

**5:15 pm – 5:30 pm** Recap and Closing Remarks for Day 1  
*David Wholley (FNIH)*

**5:30 pm – 6:30 pm** Networking Reception



## **Partnership to Address the Opioid Crisis Face-to-Face Meeting**

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### **Agenda**

## **December 13th**

### **WEBEX TO BE ADDED**

Meeting number (access code):

Meeting password:

- |                            |   |
|----------------------------|---|
| <b>7:30 am – 8:00 am</b>   | Registration and Breakfast  |
| <b>8:00 am – 8:15 am</b>   | Welcome and Introduction to Day 2<br><i>David Wholley (FNIH)</i>                                  |
| <b>8:15 pm – 12:30 pm</b>  | Focus Area B: Development of New Pain Medications Working Groups                                  |
| <b>8:15 am – 10:15 am</b>  | Biomarkers Working Group<br><i>Co-Chairs - Mark Mintun (Lilly), David Thomas (NIDA)</i>           |
| <b>10:15 am – 10:30 am</b> | Break   |
| <b>10:30 am – 12:30 pm</b> | Data Sharing Working Group<br><i>Co-Chairs - John Dunlop (Amgen), Michael Oshinsky (NINDS)</i>    |
| <b>12:30 pm – 1:15 pm</b>  | Lunch   |
| <b>1:15 pm – 3:00 pm</b>   | Focus Area B: Refinement and Budgeting<br><i>All Attendees</i>                                    |
| <b>3:00 pm – 3:15 pm</b>   | Focus Area B: Next Steps and Timelines for White Paper Development<br><i>David Wholley (FNIH)</i> |
| <b>3:15 pm – 4:00 pm</b>   | Closing Remarks   |
| <b>3:15 pm – 3:30 pm</b>   | Summary of Focus Area A<br><i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i>                          |



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**Wednesday December 13<sup>th</sup> – 7:30 AM – 4:00 PM**

### **Agenda**

**3:30 pm – 3:45 pm**      Summary of Focus Area B  
*Walter Koroshetz (NINDS) [David Wholley (FNIH)]*

**3:45 pm – 4:00 pm**      Closing Remarks  
*Francis Collins (NIH)*

**4:00 pm**                      Adjourn

DRAFT

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 28 Nov 2017 21:08:27 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** Opioids Face-to-Face Meeting Invitation  
**Attachments:** Partnership on Opioid and Pain - F2F Invitation List.xlsx

Dear All –

This is regarding the December 12-13 face to face. Can you please see below and let us know asap:

(b) (5)

We really need your feedback asap, preferably this evening (we can send out additional invitations a bit later if needed of course). Please copy Mike Biarnes on your replies.  
Thanks, David

---

**From:** Biarnes, Michael (FNIH) [T]  
**Sent:** Monday, November 27, 2017 1:42 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** Opioids Face-to-Face Meeting Information

Hi David,

As discussed, we are working to send out the face-to-face meeting registration information to all members of Focus Area 1 and 2 today or tomorrow. In order to do so, a few items need to be finalized for the registration website:

- Title of the Partnership – (b) (5)
- Meeting Overview (*Suggested language below*)
- Invitation list (*compiled FA 1 and FA 2 list attached*)

Please let me know your thoughts so that we can finalize these items and get the registration information sent out to all of the working group members.

Thanks,  
Mike

**Draft Meeting Overview for the Registration Site:**

**We've moved! Please find our new address below.**

**Michael Biarnes**

Scientific Project Manager

**Foundation for the National Institutes of Health**

(301) 594-2612

[fnih.org](http://fnih.org)

**11400 Rockville Pike Suite 600 North Bethesda, MD 20852**

*The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.*



**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 6 Oct 2017 22:24:08 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** Opioids partnership next steps

Francis, as requested:

(b) (5)





**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 11 Jun 2017 20:41:25 -0400  
**To:** Ryan, Laurie (NIH/NIA) [E]; Decker, Mike (michael.w.decker@abbvie.com)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Hodes, Richard (NIH/NIA) [E]; Petanceska, Suzana (NIH/NIA) [E]  
**Subject:** Order of slides for tomorrow morning's EC call

Laurie and Mike:

Just fyi, I have AMP AD going second tomorrow, right after the AMP PD launch update, in keeping with our past rotation of order of presentation for the three existing AMP initiatives. I wanted to let you know that when I re-sorted the slides I accidentally switched the order of the first two of the three slides featuring your comments on (b) (5) I apologize: I was doing this pretty early Pacific Time Friday morning before the AMP T2D meeting in San Diego and was a little foggy I guess. Rather than re-send the slides at this late date, I will simply mention it at the start of the meeting tomorrow. Hope that's OK. David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 3 Mar 2017 17:11:42 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** PACT and PhRMA

Francis:  
Spoke to

(b) (4)

(b) (4)

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 2 Jun 2017 18:57:42 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Lowy, Douglas (NIH/NCI) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** PACT callbacks so far

(b) (4)


(b) (4) Please let me know if we can be of further help in any way, and have a great weekend.

David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Mar 2017 17:01:37 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Lowy, Douglas (NIH/NCI) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** PACT discussion with (b) (4), (b) (6)

Hi Francis, Doug, and Jim:

(b) (4), (b) (5)



Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 17 Oct 2017 18:50:32 +0000  
**To:** Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]  
**Cc:** Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Johnson, Ellie (NIH/NIDA) [E]  
**Subject:** RE: NINDS action items from friday

Per Linda's note, we are inviting Dunlop to be industry chair of pain (focus area 2), with Verburg and Dawson as backups in the event Dunlop cannot do it.

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---

**From:** Koroshetz, Walter (NIH/NINDS) [E]  
**Sent:** Tuesday, October 17, 2017 2:48 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Johnson, Ellie (NIH/NIDA) [E] (b) (6)  
**Subject:** RE: NINDS action items from friday

Ken Verburg, John Dunlop and Kate Dawson came to the NAM meeting and seem fully engaged from the pain side.  
walter

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 17, 2017 6:47 AM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)  
**Cc:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Johnson, Ellie (NIH/NIDA) [E]

(b) (6) >

**Subject:** RE: NINDS action items from friday

Looks reasonable to me. Presentations must be really concise, don't want to compromise the discussion time. As with prior iterations of this plan, it would be good to prime a few participants to start the discussion so that there are not crickets when we get to that part.

FC

---

**From:** Baker, Rebecca (NIH/OD) [E]

**Sent:** Monday, October 16, 2017 6:09 PM

**To:** Volkow, Nora (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E]

(b) (6)

**Cc:** Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Tabak, Lawrence (NIH/OD) [E]

(b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie

(NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]

(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Burklow, John (NIH/OD)

[E] (b) (6); Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>; Menetski, Joseph (FNIH)

[T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>; Johnson, Ellie (NIH/NIDA) [E] (b) (6)

**Subject:** RE: NINDS action items from friday

Nora, to facilitate discussion, and based on our call this afternoon, I developed a draft agenda (attached).

Others please feel free to weigh in.

Thanks,  
Rebecca

---

**From:** Volkow, Nora (NIH/NIDA) [E]

**Sent:** Monday, October 16, 2017 4:28 PM

**To:** Porter, Linda (NIH/NINDS) [E] (b) (6) >

**Cc:** Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Baker, Rebecca (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis

(NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6);

Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E]

(b) (6); Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T]

<[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>; Johnson, Ellie (NIH/NIDA) [E]

(b) (6)

**Subject:** Re: NINDS action items from friday

David and Walter. I am on meetings until 8 pm. Could we speak on the phone later tonight perhaps 8:30; to touch base since we have such limited time to organize this. Nora

Sent from my iPhone

On Oct 16, 2017, at 4:07 PM, Porter, Linda (NIH/NINDS) [E] (b) (6) wrote:

David

A few changes from our follow-up emails

---

**From:** Porter, Linda (NIH/NINDS) [E]

**Sent:** Sunday, October 15, 2017 6:08 PM

**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6) Koroshetz, Walter (NIH/NINDS) [E]

(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)

**Cc:** Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>

**Subject:** NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)



Linda



**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 20 Jun 2017 13:43:53 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Melencio, Cheryl (FNIH) [T]  
**Subject:** RE: Not at PACT meeting on Thursday

Thank you for letting me know. It will just be me from our side, fyi. Stacey is in San Diego co-presenting on partnerships with Chandra Ramathan, the Bayer representative to PACT.

**David Wholley**  
**Director, Research Partnerships**  
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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, June 20, 2017 12:39 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T]  
<dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** FW: Not at PACT meeting on Thursday

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Tuesday, June 20, 2017 10:37 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Not at PACT meeting on Thursday

Hi Francis,

Please accept my apologies, but scheduling conflicts will prevent me from participating in the PACT meeting on Thursday afternoon. Jim and Anne will be there. I share your optimism that reducing the "entry fee" will produce agreements with several companies and lead to real progress.

Thanks,  
Doug

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 5 Dec 2017 18:28:43 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: note for Janet  
**Attachments:** Opioids Design Phase F2F Dec 2017 Agenda - DRAFT 05Dec2017.docx

Here you go

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, December 5, 2017 1:04 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: note for Janet

Trying that again - I'm pretty sure Janet will ask to see the agenda for Dec. 12 and 13, in order to decide which parts she might be able to attend. Can you send that?

FC

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, December 05, 2017 1:03 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: note for Janet

Tyhan,

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, December 05, 2017 10:39 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** note for Janet

Francis—draft note you requested below

Hi Janet –

I am writing to check in with you about the Opioids Partnership in-person meeting that FNIH is holding on December 12-13 next week at the Bethesda Marriott. We did our best to find dates that would work, but inevitably conflicts arise, and one of these apparently is a meeting that FDA is holding on packaging and disposal standards for opioids on December 11 and 12. My understanding is that this could have affect FDA attendance on the 12<sup>th</sup> in particular, involving schedules of Sharon Hertz and Ellen Fields in particular. I think reasonably senior FDA involvement would be important to send the right signal to the public and to our industry partners in particular. In that light, would you be willing to be there on the 12<sup>th</sup>? If not, can you help identify someone suitable to represent FDA at this critical juncture in our efforts?

Regards,  
Francis

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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| <b>8:15 am – 8:30 am</b>   | Welcome and Introduction<br><i>Francis Collins (NIH)</i>  |
| <b>8:30 am – 8:45 am</b>   | Overview of Focus Area A<br><i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i>   |
| <b>8:45 am – 9:00 am</b>   | Overview of Focus Area B<br><i>Walter Koroshetz (NINDS) [David Wholley (FNIH)]</i>  |
| <b>9:00 am – 12:30 pm</b>  | Focus Area A: OUD Treatment and Overdose Prevention/Reversal<br><i>Co-Chairs: Christopher Flores (J &amp; J Consumer); Osman Cigeroglu (Pfizer)</i> |
| <b>9:00 am – 10:00 am</b>  | New Formulations/Combinations of Existing OUD Medications<br><i>TBD</i>   |
| <b>10:00 am – 10:15 am</b> | Break   |
| <b>10:15 am – 11:15 am</b> | More Potent/Longer-lasting Antagonists to Reverse Overdose<br><i>TBD</i>  |
| <b>11:15 am – 12:15 pm</b> | Alternative Endpoints for OUD Medications<br><i>TBD</i>   |



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**Wednesday December 13<sup>th</sup> – 7:30 AM – 4:00 PM**

### **Agenda**

**12:15 pm – 12:30 pm** Focus Area A: Next Steps and Timelines for White Paper Development  
*TBD*

**12:30 pm – 1:00 pm** Lunch

**1:00 pm – 5:30 pm** Focus Area B: Development of New Pain Medications Working Groups

**1:00 pm – 3:00 pm** Asset Repurposing Working Group  
*Co-Chairs – Chris Austin (NCATS), Chris Flores (Johnson & Johnson)*

**3:00 pm – 3:15 pm** Break

**3:15 pm – 5:15 pm** Clinical Trials Network Working Group  
*Co-Chairs - Linda Porter (NINDS), Kenneth Verburg (Pfizer), Clinton Wright (NINDS)*

**5:15 pm – 5:30 pm** Recap and Closing Remarks for Day 1  
*David Wholley (FNIH)*

**5:30 pm – 6:30 pm** Networking Reception



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### **Agenda**

#### **December 13<sup>th</sup>**

##### **WEBEX TO BE ADDED**

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Meeting password:

- |                            |   |
|----------------------------|---|
| <b>7:30 am – 8:00 am</b>   | Registration and Breakfast  |
| <b>8:00 am – 8:15 am</b>   | Welcome and Introduction to Day 2<br><i>David Wholley (FNIH)</i>                                  |
| <b>8:15 pm – 12:30 pm</b>  | Focus Area B: Development of New Pain Medications Working Groups                                  |
| <b>8:15 am – 10:15 am</b>  | Biomarkers Working Group<br><i>Co-Chairs - Mark Mintun (Lilly), David Thomas (NIDA)</i>           |
| <b>10:15 am – 10:30 am</b> | Break   |
| <b>10:30 am – 12:30 pm</b> | Data Sharing Working Group<br><i>Co-Chairs - John Dunlop (Amgen), Michael Oshinsky (NINDS)</i>    |
| <b>12:30 pm – 1:15 pm</b>  | Lunch   |
| <b>1:15 pm – 3:00 pm</b>   | Focus Area B: Refinement and Budgeting<br><i>All Attendees</i>                                    |
| <b>3:00 pm – 3:15 pm</b>   | Focus Area B: Next Steps and Timelines for White Paper Development<br><i>David Wholley (FNIH)</i> |
| <b>3:15 pm – 4:00 pm</b>   | Closing Remarks   |
| <b>3:15 pm – 3:30 pm</b>   | Summary of Focus Area A<br><i>Nora Volkow (NIDA) [Jack Stein (NIDA)]</i>                          |



## **Partnership to Address the Opioid Crisis Face-to-Face Meeting**

Bethesda North Marriott Hotel – 5701 Marinelli Road, Rockville, MD 20852

**Tuesday December 12<sup>th</sup> – 7:30 AM – 6:30 PM**

**Wednesday December 13<sup>th</sup> – 7:30 AM – 4:00 PM**

### **Agenda**

**3:30 pm – 3:45 pm**      Summary of Focus Area B  
*Walter Koroshetz (NINDS) [David Wholley (FNIH)]*

**3:45 pm – 4:00 pm**      Closing Remarks  
*Francis Collins (NIH)*

**4:00 pm**                      Adjourn

DRAFT

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 17:02:43 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: note to Janet Woodcock

After I get off the latest opioid call, sure

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, December 4, 2017 11:48 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: note to Janet Woodcock

Will do. In a total crunch today, can you send me a draft message that I could quickly edit and send off?

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, December 04, 2017 11:42 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** note to Janet Woodcock

Francis, you asked me to remind you to reach out to Janet today regarding FDA attendance at the face to face opioids partnership meeting on December 12-13, since we have not heard back definitively from Sharon Hertz about who will attend on those dates. As a heads up/reminder: 1) FDA has had a representative on 7 of the 9 Working Group calls we have had to date, which is pretty good 2) the main issue is December 12, when FDA has its own meeting on safe packaging for opioids 3) Sharon did say she'd find someone, it just can't be her or Ellen Fields or Doug Throckmorton, and has not said who yet. Therefore, I would probably soft shoe this a bit with Janet rather than complain we don't have anyone—you understand there is an important meeting that day, FDA challenged to find people to come on the 12<sup>th</sup>, perhaps Janet would like to attend herself since you will be there... etc.

Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 17:23:02 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: note to Janet Woodcock

For what? No problem!

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, December 4, 2017 12:11 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: note to Janet Woodcock

Sorry!

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, December 04, 2017 12:03 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: note to Janet Woodcock

After I get off the latest opioid call, sure

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, December 4, 2017 11:48 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: note to Janet Woodcock

Will do. In a total crunch today, can you send me a draft message that I could quickly edit and send off?

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, December 04, 2017 11:42 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** note to Janet Woodcock

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 27 Jun 2017 17:02:26 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: AMP Extended EC 6-30-2017 v2 - DRAFT 6-23.pptx

No problem, Francis. Sounds like a worthy (and fun) endeavor. I like your plan on the intro slides (though it is really slides 3-8 as my roll call will cover who is participating). Hope we can get Mikael to net it out this time...By the way (b) (6) but has asked Andy Dahlem to stand in for him. (b) (4), (b) (6) cannot make the call but has confirmed his interest in representing BMS on the EEC. Spyros Artavanis-Tsakonas left Biogen last month; Mike Ehlers has confirmed he will replace Spyros on the EEC, though neither he nor his backup, Anirvan Ghosh, will be available Friday morning. They all know about the December call. I will join you in your office for the call if OK. Thanks, David

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, June 27, 2017 3:39 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: AMP Extended EC 6-30-2017 v2 - DRAFT 6-23.pptx

Hi David,

Sorry about the slow response, (b) (6)

The slides look fine, though the presenters for each project will have to move forward efficiently to keep from falling behind.

What about the introduction? There's only 5 minutes budgeted for slides 2 – 8. Once before we had a problem with Mikael taking much too long. Shall I e-mail with him and make a plan? Perhaps he can do 2 – 5, I can do 6 – 8?

I plan to be at NIH in person on Friday at 7 AM.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, June 23, 2017 6:34 PM

**To:** Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)

**Subject:** AMP Extended EC 6-30-2017 v2 - DRAFT 6-23.pptx

Hi Francis –

Here are the draft slides for the Extended EC teleconference next Friday June 30. If you have time to take a look, please let me know if you have any comments or suggestions. Unless you disagree I would plan to send the complete text document with the [REDACTED] (b) (5) responses along with these as a pre-read, so would plan to send out no later than Tuesday. Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 12 Dec 2017 02:34:54 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** Re: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Got it.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, December 11, 2017 9:33 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi David,

Wow, this is better but still seems overly detailed. With 66 slides I fear it will be hard to preserve much time for discussion in our 90 minute call.

Not including the title slides, I count 12 slides for T2D, 21 for RA/SLE, and 15 for AD. That makes me worry most about RA/SLE. I don't see how the team can present 21 data slides in 15 minutes without frustrating the listeners. Can you ask Bob Carter to consider this one more time, and potentially drop a few slides that are not essential? Slides 37 and 38 look like candidates for deletion to me.

Remembering a prior EEC where the introductory remarks from Mikael were elegant and inspiring, but went on WAY too long, shall I reach out to him to divide up that part, and emphasize that the introductory remarks should be very brief? In that regard, I'd recommend dropping slide 7 – it has a lot of details, and Lon and Patrick are no longer involved. Can be referred to verbally.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, December 11, 2017 4:25 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Gadbois, Ellen (NIH/OD) [E] (b) (6); Singh, Jyoti (NIH/OD) [E]  
(b) (6); Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>  
**Subject:** AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David



**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 12 Dec 2017 02:39:42 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Morgan, Emily (FNIH) [T]  
**Subject:** Re: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

PS, yes please reach out to Mikael. Cheryl or Emily can you please make the deletions Francis has suggested and resend him the deck to use with Mikael? Thanks  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, December 11, 2017 9:33 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Gadbois, Ellen (NIH/OD) [E]; Singh, Jyoti (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** RE: AMP Extended EC 12-15-2017 2nd DRAFT.pptx

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FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, December 11, 2017 4:25 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Gadbois, Ellen (NIH/OD) [E] (b) (6); Singh, Jyoti (NIH/OD) [E]  
(b) (6) Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>  
**Subject:** AMP Extended EC 12-15-2017 2nd DRAFT.pptx

Hi Francis – As requested, here is the second pass at the slides for the AMP EEC this Friday. We've done our best to work with the co-chairs to prune and improve the slides per your feedback on last week's pre-call. Let us know what you think, including where you think there are any additional opportunities for condensing this. Thanks, David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 11 Jun 2017 22:14:55 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: AMP Extended EC attendee slide.pptx

Will do

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, June 11, 2017 8:52 PM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** RE: AMP Extended EC attendee slide.pptx

That's encouraging, except for Lundberg – [REDACTED] (b) (5)

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sunday, June 11, 2017 8:50 PM  
**To:** Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6)  
**Subject:** AMP Extended EC attendee slide.pptx

Hi Francis, just thought you'd want to know we have pretty good attendance projected for the Extended EC on June 30 – except for Jan Lundberg, [REDACTED] (b) (6) and Jim Sullivan of AbbVie, who had been tentative but will likely not be able to attend. I can ask both of them to appoint alternates if you wish. FYI, [REDACTED] (b) (4) just responded positively on Thursday. Thanks, David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sat, 25 Mar 2017 13:43:29 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Sutherland, Margaret (NIH/NINDS) [E]; Canet-Aviles, Rosa (FNIH) [T]  
**Subject:** RE: AMP PD next steps

Yes, I saw your note, Francis, and thank you very much for pushing this. Meanwhile, is it OK if we push forward to get the project planning meeting scheduled? We'll need to begin now for mid- to late April dates (we are looking for a venue now).

Regards, David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, March 24, 2017 4:13 PM  
**To:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6) Wholley, David (FNIH) [T]  
<dwholley@fnihi.org>  
**Cc:** Sutherland, Margaret (NIH/NINDS) [E] (b) (6); Canet-Aviles, Rosa (FNIH) [T]  
<rcanet-aviles@fnihi.org>  
**Subject:** RE: AMP PD next steps

I am too, but let me try one more time with (b) (4)

---

**From:** Koroshetz, Walter (NIH/NINDS) [E]  
**Sent:** Friday, March 24, 2017 1:41 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Sutherland, Margaret (NIH/NINDS) [E] (b) (6); Canet-Aviles, Rosa (FNIH) [T]  
<rcanet-aviles@fnihi.org>  
**Subject:** RE: AMP PD next steps

Yes, I am in favor of moving now.  
walter

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, March 24, 2017 1:40 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6)  
**Cc:** Sutherland, Margaret (NIH/NINDS) [E] (b) (6); Canet-Aviles, Rosa (FNIH) [T]  
<rcanet-aviles@fnihi.org>  
**Subject:** AMP PD next steps  
**Importance:** High

Hi Walter and Francis:

(b) (4)  
(My last ping was a week ago; radio silence since.)  
I am not reading anything in particular into this (I think she is just having trouble corralling everyone who'd need to support this internally), but on our side I think we need to begin moving forward with the



partners we have. Some additional work on some of the MJFF samples has already begun (RNA sequencing, some proteomics pilots and the like),

(b) (4)

(b) (4)

Rosa and I just got off a phone call with Todd Sherer and Marg Sutherland where we discussed the first two issues in particular, and Todd agrees strongly with moving AMP PD forward now. This would take the form of FNIH putting together a face to face meeting with our five existing partners (NIH/NINDS, GSK, MJFF, Pfizer, and Verily) to figure out how we apply the \$16M/5 years currently committed to the program in the form of a revised research plan based on the white paper, but with more detailed logistics, budgets, milestones, governance structure, etc. etc. (just as we did with the other three AMPs).

(b) (4)

(b) (4)

Right now we are thinking of having this meeting in mid to late April if we can round up everyone's calendars. While we'd likely want to wait until after the meeting for any formal announcement, if we can just get it scheduled I think we could begin informally to signal to those who may be interested that this is moving forward (say, at the HEVER meeting).

Are you in favor of doing this? Is there anything else you'd like us to do prior to getting this going?

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 9 Apr 2017 15:19:49 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: AMP-PD

Whew

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 9, 2017 3:17 PM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** RE: AMP-PD

Yes, that's coming next, mostly good...

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sunday, April 09, 2017 3:17 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Re: AMP-PD

Anything on PACT, Francis?

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 9, 2017 2:43 PM  
**To:** Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]  
**Subject:** AMP-PD

Hi David and Walter,

I was very happy to be able to present AMP-PD at Hever yesterday, and to announce that we have our five participants (GSK, Pfizer, Sanofi, MJFF, and Verily). (b) (4)

I had a vague sense that there might just be one or two other companies that would be interested in joining now – and I wouldn't want to miss the chance to reach out, just in case. (b) (5)

-  
The message should include appropriate documentation about the current plan.

Is it time now to approach Sergey Brin about the original project 1 (iPS etc.)?

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 9 Apr 2017 15:16:59 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: AMP-PD

Anything on PACT, Francis?

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 9, 2017 2:43 PM  
**To:** Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]  
**Subject:** AMP-PD

Hi David and Walter,

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[REDACTED] -  
[REDACTED] The message should include appropriate documentation about the current plan.

Is it time now to approach Sergey Brin about the original project 1 (iPS etc.)?

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 9 Apr 2017 15:02:39 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Canet-Aviles, Rosa (FNIH) [T]  
**Subject:** Re: AMP-PD

Sure.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 9, 2017 2:43 PM  
**To:** Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]  
**Subject:** AMP-PD

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FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 10 Apr 2017 21:15:02 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]  
**Subject:** RE: AMP-PD

I should have something to you tomorrow.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 09, 2017 2:44 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** AMP-PD

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The message should include appropriate documentation about the current plan.

Is it time now to approach Sergey Brin about the original project 1 (iPS etc.)?

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 3 Oct 2017 13:00:16 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
**Subject:** Re: An idea: getting drug companies to share negative data

My view: perhaps.

(b) (5)

(b) (5)

Sent from my BlackBerry 10 smartphone.

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 3, 2017 6:57 AM  
**To:** Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
**Subject:** Fwd: An idea: getting drug companies to share negative data

(b) (5)

Sent from my iPhone

Begin forwarded message:

**From:** "Ed Boyden, [esb@media.mit.edu](mailto:esb@media.mit.edu)" (b) (6)  
**Date:** October 3, 2017 at 5:43:51 AM EDT  
**To:** "Volkow, Nora (NIH/NIDA) [E]" (b) (6)  
**Cc:** Katharina Sophia Volz <[volz@occamzrazor.com](mailto:volz@occamzrazor.com)>, kaya c tilev <[kaya@occamzrazor.com](mailto:kaya@occamzrazor.com)>, "Collins, Francis (NIH/OD) [E]" (b) (6), Bertha Madras (b) (6)  
**Subject:** Re: An idea: getting drug companies to share negative data  
**Reply-To:** (b) (6)

Dear Francis, Nora, Bertha,

Building from your great feedback -- we have sketched out a brief article -- which we may extend, and submit for publication, but wanted your early reactions -- about the open questions relating to creating a market for negative data in biomedicine. The goal was to understand the conditions that must be fulfilled, in order for this idea to have a feasible economic trajectory. Obviously there are a lot of uncertainties relating to how such an idea would be deployed, and feedback from potential participants in the market could be useful (or maybe the right next step would be just "giving it a try").



We would love to hear your thoughts, if you might have a moment!

Best,  
Ed

On Wed, Jul 19, 2017 at 2:46 PM, Ed Boyden, [esb@media.mit.edu](mailto:esb@media.mit.edu)

(b) (6) wrote:

Thanks so much for the helpful thoughts, Nora, Francis, and Bertha!  
We will work on the idea further, then, and be in touch as thoughts mature.

Best,  
Ed

On Fri, Jul 14, 2017 at 3:09 PM, Volkow, Nora (NIH/NIDA) [E]

(b) (6) wrote:

Dear Ed: I like the concept because I agree that this would incentivize sharing of data (perhaps even compounds) that otherwise would remain in "drug and data cemeteries". Of course, the trick will be on the details of how to make it work. nora

On 7/13/17, 9:30 AM, "Ed Boyden, [esb@media.mit.edu](mailto:esb@media.mit.edu)" (b) (6) wrote:

Dear Francis, Bertha, Nora,

There's clearly a lot of inertia related to the problem of getting drug companies to open up more, especially regarding sharing negative data. A few of us (cc'ing Katharina and Kaya, at the new startup company Razor, Inc., which I advise) have been thinking about a new idea: to create a \*market\* for negative data. What if, say, we created a secure environment for the storage of the data, and then a team (under nondisclosure) could mine the data for interesting clues? Then, new drugs could be invented taking advantage of the new information. Suppose, say, 60% of the profits would go to the company developing the new drug, but the other 40% would be split between the companies whose negative data contributed. It would be split up in a fair way that would take into account the cost to produce this data (in vitro, in vivo for preclinical or Phase I, II or III for clinical trials). This would incentivize sharing. Key to this working would be a way to track the flow of information to assign credit properly -- something the Razor team has started to think about, at a software level. What do you think? Hope all is well!

Best,  
Ed

--

Ed Boyden, Ph. D.

Leader, Synthetic Neurobiology Group

Associate Professor, MIT Media Lab and McGovern Institute,

Departments of Biological Engineering and Brain and Cognitive Sciences

Co-Director, MIT Center for Neurobiological Engineering

Massachusetts Institute of Technology

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email - [esb@media.mit.edu](mailto:esb@media.mit.edu)  
phone - (617) 324-3085  
cell - (b) (6)  
fax - (617) 253-6285  
Google Hangout - (b) (6)  
skype - eboyden3  
web - <http://syntheticneurobiology.org>  
twitter - <http://twitter.com/eboyden3>

--

Ed Boyden, Ph. D.  
Leader, Synthetic Neurobiology Group  
Associate Professor, MIT Media Lab and McGovern Institute,  
Departments of Biological Engineering and Brain and Cognitive Sciences  
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fax - (617) 253-6285  
Google Hangout - (b) (6)  
skype - eboyden3  
web - <http://syntheticneurobiology.org>  
twitter - <http://twitter.com/eboyden3>

--

Ed Boyden, Ph. D.  
Leader, Synthetic Neurobiology Group  
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fax - (617) 253-6285  
Google Hangout - (b) (6)  
skype - eboyden3



web - <http://syntheticneurobiology.org>  
twitter - <http://twitter.com/eboyden3>

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 21 Mar 2017 17:29:51 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]  
**Subject:** RE: Another AMP project?

Hi Francis:

I solemnly promise not to freak out.

I think it is at least worth a try.

(b) (5)

(b) (5)

If we were going to design something we'd need a bit of seed funding from the interested partners similar to the way we approached AMP and PACT.

Thanks for asking me.

David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, March 21, 2017 4:02 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]  
(b) (6)  
**Subject:** Another AMP project?

Hi David,

(b) (5)

(b) (5)

Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 16 Nov 2017 13:30:47 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Subject:** RE: Another Time Sensitive Request: Opioid Partnership Co-Chair

He's been pretty involved in the pain discussions>

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, November 15, 2017 6:44 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]  
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Subject:** FW: Another Time Sensitive Request: Opioid Partnership Co-Chair

Well, that one didn't go through.

---

**From:** Pamela J Edmonds [[mailto:edmonds\\_pamela\\_j@lilly.com](mailto:edmonds_pamela_j@lilly.com)] **On Behalf Of** Jan Lundberg  
**Sent:** Wednesday, November 15, 2017 5:26 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Daniel Skovronsky <[skovronsky\\_daniel@lilly.com](mailto:skovronsky_daniel@lilly.com)>; Timothy Garnett <[garnett\\_tim@lilly.com](mailto:garnett_tim@lilly.com)>; Mark Mintun <[mintun@avidrp.com](mailto:mintun@avidrp.com)>; David A Ricks <[ricks\\_david@lilly.com](mailto:ricks_david@lilly.com)>; Andrew H Ahn <[andyahn@lilly.com](mailto:andyahn@lilly.com)>  
**Subject:** RE: Another Time Sensitive Request: Opioid Partnership Co-Chair

Dear Francis,

Thank you for your recent email concerning (b) (4) availability to consult more extensively on the work group developing new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose. As you well know, (b) (4) is already co-chairing one half of the group that is looking at developments in non-opioid pain medications. This really reflects both (b) (4) and Lilly's current expertise. Andy Ahn from Lilly is also a member of the opioid work group to learn more about the difference between addictive and non-addictive pain mechanisms. We believe that if the work to develop new formulations and combinations of medications to treat opioid use disorders, and prevent overdose is to be truly effective, it really needs to be led by, and primarily leverage experts from biopharma companies who are active in the opioid field.

In addition, this work and (b) (4) current responsibilities here at Lilly would really preclude him from being able to commit any further time to the efforts in the short-term.

Best,

Jan

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Thursday, November 09, 2017 6:44 PM  
**To:** Jan Lundberg <lundberg\_jan@lilly.com>  
**Cc:** Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** [EXTERNAL] Another Time Sensitive Request: Opioid Partnership Co-Chair

Dear Jan,

Thank you again for agreeing for (b) (4) to serve in this role.

As we continue our planning process for this partnership to bring about early successes in the opioid crisis, we have thought more about the potential value of having (b) (4) provide advice toward our first and more near-term goal: to develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose.

The additional time commitment for (b) (4) would include 2-3 teleconferences and attendance at the one in-person meeting, now planned for early December, that will address both the pain and addiction focus areas. In this effort, (b) (4) would work with Nora Volkow, the Director of the National Institute on Drug Abuse and her staff in the initial design phase for this focus area of the partnership.

Would you be willing to consider (b) (4) in this additional role? As always, I would be happy to discuss further or answer any questions you may have. I have copied Nora Volkow and Jack Stein of NIDA, who are helping lead this effort as well. Given our very abbreviated time table, I would be grateful to hear back from you on this by the middle of next week.

Warm regards,  
Francis

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, November 1, 2017 6:12 PM  
**To:** Jan Lundberg <lundberg\_jan@lilly.com>  
**Cc:** Mark Mintun <mintun@avidrp.com>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); David A Ricks <ricks\_david@lilly.com>  
**Subject:** RE: [EXTERNAL] Time Sensitive Request: Opioid Partnership Co-Chair

That's great news, thanks!

Best, Francis

---

**From:** Jan Lundberg [mailto:lundberg\_jan@lilly.com]  
**Sent:** Wednesday, November 01, 2017 1:48 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Mark Mintun <mintun@avidrp.com>; Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); David A Ricks <ricks\_david@lilly.com>  
**Subject:** Re: [EXTERNAL] Time Sensitive Request: Opioid Partnership Co-Chair

Francis, we are very positive to (b) (4) leading topic 2 :non addictive pain therapies and he has also agreed. So please move on in this highly needed area of new better and safer medicines!

Best

Jan

Sent from my iPhone

On Oct 31, 2017, at 2:16 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Dear Jan,

I am writing to you today about a new partnership effort, this one with FDA and as many as 30 potential company partners to address the national opioid abuse crisis. We have made considerable progress in defining an initial research agenda, and are at point of convening our partners to refine it into a final design over the next several months. I am writing to ask if (b) (4) could play a key leadership role in this effort.

As a result of our discussions to date—in which (b) (4) participated--we've selected two focus areas for the partnership:

1. Develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose
2. Develop new non-addictive pain therapies.

The next steps involve convening a Working Group of experts from NIH, the interested industry partners, and several key academic opinion leaders to agree on the research plan. We are looking to select one industry scientist and one NIH representative to co-chair each of the Working Groups. Both Walter Koroshetz and Linda Porter of NIH's National Institute of Neurological Disorders and Stroke enthusiastically recommended Mark to serve as the industry co-chair for focus area #2 in developing new pain therapies.

The time commitment for (b) (4) would entail 3-4 teleconferences (a couple of hours each) and at least one in-person, full-day meeting in late November or early December, with the key deliverable being a white paper describing the consensus of the group on a common mission and a high-level plan. Given



the magnitude of the crisis, and the strong interest of the current Administration and the Congress, we'd like to solidify a plan and gather the necessary funding commitments by the end of this year, with a view to funding and launching an effort in early 2018. We are engaging the Foundation for the NIH to manage this effort, and (b) (4) would be fully staffed by FNIH to make this successful.

Would you be willing to consider (b) (4) in this role? I will be happy to answer any questions you may have or discuss further, and am copying David Wholley at FNIH, who is helping lead this effort, as well. I hope I will hear back from you on this by the middle of next week.

Warm regards,  
Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 30 Jun 2017 14:07:47 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Any feedback you can give me from yesterday's meeting

I just spoke to Tom.

(b) (4)

(b) (4)

(b) (4) That is, if rational arguments work

at all. Tom asked to be kept abreast of outcome on this, fyi. Thanks as always. David  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 30, 2017 10:58 AM  
**To:** Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]  
**Subject:** RE: Any feedback you can give me from yesterday's meeting

Oy. (b) (4) I will.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, June 30, 2017 9:10 AM  
**To:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]  
(b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>  
**Subject:** Fw: Any feedback you can give me from yesterday's meeting

(b) (4)

(b) (4) I will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

Let me know if you'd like me to pull together a strategy call for next week sometime. It would be smart to involve Todd Sherer too, though I know he's left on his vacation as of early this week.



David

Sent from my BlackBerry 10 smartphone.

---

**From:** William Marks (b) (6)  
**Sent:** Friday, June 30, 2017 8:46 AM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** David Glazer  
**Subject:** Re: Any feedback you can give me from yesterday's meeting

Hi, David.

(b) (4)

(b) (4) David, I, and the team are regrouping later today to work further on this. We will keep you posted as we know more. I'm sorry for this less than happy news.

Bill

On Jun 30, 2017 3:38 AM, "Wholley, David (FNIH) [T]" <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)> wrote:

Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David  
Sent from my BlackBerry 10 smartphone.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 30 Jun 2017 11:03:45 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]  
**Subject:** RE: Any feedback you can give me from yesterday's meeting

Yes, I think it would. (b) (4)  
(b) (4)  
(b) (4). We'd need to get this done by midweek next week I think in any case.

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 30, 2017 10:58 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>  
**Subject:** RE: Any feedback you can give me from yesterday's meeting

Oy. (b) (4), I will.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, June 30, 2017 9:10 AM  
**To:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]  
(b) (6) Sutherland, Margaret (NIH/NINDS) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>  
**Subject:** Fw: Any feedback you can give me from yesterday's meeting

(b) (4)  
(b) (4) will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

Let me know if you'd like me to pull together a strategy call for next week sometime. It would be smart to involve Todd Sherer too, though I know he's left on his vacation as of early this week.

David

Sent from my BlackBerry 10 smartphone.

---

**From:** William Marks (b) (6)

**Sent:** Friday, June 30, 2017 8:46 AM

**To:** Wholley, David (FNIH) [T]

**Cc:** David Glazer

**Subject:** Re: Any feedback you can give me from yesterday's meeting

Hi, David.

(b) (4)

(b) (4)

David, I, and the team are regrouping later today to work further on this. We will keep you posted as we know more. I'm sorry for this less than happy news.

Bill

On Jun 30, 2017 3:38 AM, "Wholley, David (FNIH) [T]" <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)> wrote:

Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David  
Sent from my BlackBerry 10 smartphone.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 30 Jun 2017 17:18:46 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Any feedback you can give me from yesterday's meeting  
**Attachments:** Technical Plan for AMP PD knowledge portal.pdf

Hi, Francis:

Thanks for responding so late on holiday Friday. Unfortunately I do not have a phone number or email for Andy, and my search (Google of course...) of the web has turned up nothing. Judging by the email addresses I have seen of other Verily employees, you might try (b) (6) or (b) (6). Otherwise my only other recourse would be Cheryl who is out of the office until Wednesday at this point.

As for Verily's role: as you know, AMP PD is designed to identify and develop biomarkers that can be used to support design of PD clinical trials, taking advantage of already existing clinically phenotyped, longitudinal, genetically characterized PD cohorts with linked longitudinal biobanks (*PPMI, PDBP, Harvard Biomarkers Study, PARS, and others*). Proposed assays include deep molecular characterization, neuroimaging, multimodal imaging, and profiling of PD patients. The proposal includes a plan for open data access and sharing to dissect new targets, disease subtypes, and markers that track and predict progression. All the results will be made broadly available through an AMP-PD Knowledge Platform. Verily has proposed to provide in-kind software development and services to support data management, analytical pipelines, and visualization tools. They were to have included cloud-based hosting services for the Knowledge Platform as part of this, but that element is actually not nearly as important as the analytical software development piece—which they could potentially reuse across any number of similar projects. Although it is rather dated (still includes Proposal 1 for example) the attached Technical Plan we sent them over the winter really is not too different from the current requirements Verily would be addressing from an informatics point of view.

On another subject, Stacey Adam and I spoke with Edith Perez, the CMO of Genentech, about a half hour ago regarding PACT. (b) (4)

(b) (4)

Thanks, David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 30, 2017 3:02 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** RE: Any feedback you can give me from yesterday's meeting

Will do.

Might you have a phone number or e-mail? I don't seem to have readily available.

I need to understand better what Verily's actual role was supposed to be. Can you help me with that?

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, June 30, 2017 2:08 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Re: Any feedback you can give me from yesterday's meeting

I just spoke to Tom. (b) (4)

(b) (4)

(b) (4) That is, if rational arguments work at all. Tom asked to be kept abreast of outcome on this, fyi. Thanks as always. David  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 30, 2017 10:58 AM  
**To:** Wholley, David (FNIH) [T]; Koroshetz, Walter (NIH/NINDS) [E]; Sutherland, Margaret (NIH/NINDS) [E]  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]  
**Subject:** RE: Any feedback you can give me from yesterday's meeting

Oy. If it would help for me to reach out to Andy Conrad, I will.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, June 30, 2017 9:10 AM  
**To:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Sutherland, Margaret (NIH/NINDS) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>  
**Subject:** Fw: Any feedback you can give me from yesterday's meeting



(b) (4)

(b) (4)

I will reach out to Bill to ask for a call to ascertain more details, but any thoughts as to what we might do to mitigate the risk here? Can we point out synergies Verily may have working across NIH as part of the strategic fit? One hates to take a negative tack here, but are there indeed downside consequences for withdrawal I can point out to Bill? And is there any alternative--another in-kind technology partner we can feasibly approach?

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David

Sent from my BlackBerry 10 smartphone.

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**From:** William Marks (b) (6)

**Sent:** Friday, June 30, 2017 8:46 AM

**To:** Wholley, David (FNIH) [T]

**Cc:** David Glazer

**Subject:** Re: Any feedback you can give me from yesterday's meeting

Hi, David.

(b) (4)

(b) (4) I know this news and

lack of certainly puts you in a precarious situation. David, I, and the team are regrouping later today to work further on this. We will keep you posted as we know more. I'm sorry for this less than happy news.

Bill

On Jun 30, 2017 3:38 AM, "Wholley, David (FNIH) [T]" <[dwholley@fnih.org](mailto:dwholley@fnih.org)> wrote:

Know it is early in CA but I am in a meeting with Francis Collins and Walter Koroshetz this morning and they will ask me about where things stand...thanks, David

Sent from my BlackBerry 10 smartphone.

## Technical Plan for AMP-PD Knowledge platform

### Introduction:

The Accelerating Medicine Partnership (AMP) in Parkinson's Disease (PD) is a proposed partnership between the National Institutes of Health, industry partners and non-government organizations with the goals of executing innovative research that advances the identification and validation of new therapeutic targets for drug development and developing biomarkers that will support better clinical trial designs in PD.

The two projects that comprise the AMP-PD program; 1) Target and Assays, and 2) Clinical Biomarkers to enable Proof-of-Concept Trials. These projects are designed to be interactive, and it is anticipated that data derived from one project will help to inform directions and strategies used in the other project. The complementary nature of the 2 projects is based on shared approaches and platforms for whole genome sequencing, RNA preparation and sequencing, epigenomic analysis, proteomic and metabolomic techniques for data generation and harmonization of clinical data from multiple biomarker cohort studies that include detailed longitudinal assessment of over 5,000 PD cases and age and gender matched controls with fluid biosample collections. The key element that will link AMP-PD projects 1 and 2 and provide the interface for data access and analysis for AMP-PD investigators and the larger research community will be the AMP-PD Knowledge Platform.

The AMP-PD Knowledge Platform will support data sharing and analysis through a cloud-based infrastructure that integrates systems and tools through a common interface, and links various data types including:

- clinical data and associated imaging data
- whole genome and exome sequencing data
- RNA sequencing (RNA seq) data
- robotics imaging data
- proteomics and metabolomics mass spectrometry data
- epigenomic data
- metadata from biomarker platforms like studies, protocols, forms, cohorts, subjects, and publications

To ensure data quality and address the needs of multiple data science stakeholders, both raw and processed data will be stored in the cloud environment and quality control of data will be coordinated through the use of standardized form structures with quality control checks that include variant ranges and types built into the form structure data elements. Common data analysis pipelines are predominantly based on current large whole genome sequencing consortia strategies and various NIH Common Fund data coordinating center quality control and analysis strategies for RNA seq, proteomics, epigenomics and metabolomics data. These pipelines will be used to generate processed datasets that will be available to researchers both within and outside of AMP-PD. These processed datasets will be described and published to discovery indexes, like the NIH Big Data to Knowledge (BD2K) DataMed, and will also be used to generate a searchable aggregate database on a public site that can provide summary information, as an entry point for data discovery, for less data intensive users. Additional open source integrative data analytical tools will also be available in the cloud environment to support integrative analysis of the various data types. A cloud collaborative project management solution will be designed

to support collaborative projects with investigators both inside and outside of AMP-PD to further accelerate neurological disease research.

#### **Data currently available and estimates of data to be generated with timeline**

Much of the AMP-PD research agenda will take advantage of already existing data. The data listed in Table 1 is available now and has been used in several publications<sup>(1,2,3)</sup>. The PDGSC exome meta-analysis is ongoing and a publication should be ready for submission by early 2017. Storage and analysis of the PDGSC exome data is accomplished using Google Genomics and funding is in place to support data storage and analysis time for the next 8-10 months. Whole genome sequencing (WGS) data listed in Table 2 will be available in early 2017. Storage and analytical costs are part of the AMP-PD budget analysis. Approximately 6,000-10,000 control WGS dataset are or will be available in the first 1-2 years of AMP-PD, with data from several studies including the National Institute of Aging (NIA) NIAGAD project, the National Heart, Lung and Blood Institute (NHLBI) TopMED project, Mayo Clinic 1000 control genome project and the Wellcome Trust. RNA seq, epigenomic, proteomic, robotic imaging data and additional biomarker platform data will be available beginning in the 4<sup>th</sup> quarter of year 1 and accumulate over the duration of AMP-PD.

(b) (4)

#### **AMP-PD Knowledge Platform Requirements:**

The following is a high-level technical description of the components of the proposed AMP-PD Knowledge Platform that could be supported in-kind through Verily, and includes: 1) development of a controlled access AMP-PD Knowledge platform with considerations for data storage and management, standardized pipeline analyses for generation of processed datasets, cloud collaborative project management and where appropriate incorporation of PD3P DMR infrastructure elements to support the AMP-PD Knowledge platform; and 2) development of a AMP-PD public site.

##### **A. Controlled Access AMP-PD Knowledge Platform**

##### **Data Storage and management**

Table 2 outlines the data storage and computing times required for the various data types generated in AMP-PD Project 1 (Phase 0, Phase 1 and Phase 2) and AMP-PD Project 2. Data types will be collected




against standard form structures developed by the NINDS PDBP data management resource. These form structures are consistent with solutions used across NIH institutes and databases. Raw data will be uploaded to the cloud, processed, and reprocessed, but must be quality controlled prior to submission to the AMP-PD Knowledge Portal. This ensures all data that is managed by AMP-PD Knowledge Portal meets minimum standards of structural validation. Once in the cloud environment, an AMP-PD data coordinating group will check data quality prior to releasing the data for public use. Both raw data and processed data will be stored in the cloud environment. Clinical data currently in the NINDS data management resource and representing PDBP, PPMI, BioFIND and Harvard Biomarker Study cohorts will be moved into the cloud environment. All data sets include Global Unique Identifiers (GUIDs), which enable individual level data analysis. Selected processed datasets generated by standard analysis pipelines will be used to assemble aggregate data that will be used to populate a searchable PD variant database. This database will be accessible on a public facing website and modeled after the University of California San Diego genome browser. To address efficient data storage and associated costs, commonly requested, searched and analyzed data will be promoted for ready use, whereas less common data will be archived to a less expensive storage solution. For long term data access, beyond the period of AMP-PD, all data that is part of AMP-PD will be submitted to the NIH database for Genotypes and Phenotypes (dbGaP) and/or to a NIH Data Commons, if that solution is available within the timeframe of AMP-PD.

### **Analytical Pipelines**

Standard analytical pipelines are essential for coordinating datasets both within and across projects. Since both AMP-PD Projects 1 and 2 will be utilizing shared data-generating platforms for whole genome sequencing, RNA sequencing, epigenomics, proteomics and metabolomics, the best practice for data coordination is to apply common analytical pipelines that would allow for the specific characteristics of the different datatypes. These processed datasets would therefore, for instance, enable analyses within the datatypes generated from AMP-PD Project 1 (which includes iPSC and human tissue derived cell-based data) and AMP-PD Project 2 (which includes data generated from biofluid sample analysis). Common pipeline processes will also enable combined analyses with Project 1 and Project 2 data and will be driven by a DMR-supported authenticated controlled access dataset retrieval service interface. Standard analytical pipelines have been developed for RNA seq (e.g., see the NeuroLINCS example outlined in Figure 1), epigenomics, proteomics (e.g DIA processing and DDA library builds outlined in Figure 1) and metabolomics. These pipelines use standard file formats and open-source tool components like BWA/GATK, Bioconductor, Bioperl, BioJava, Octave, BLAST, Tophat(2), STAR,

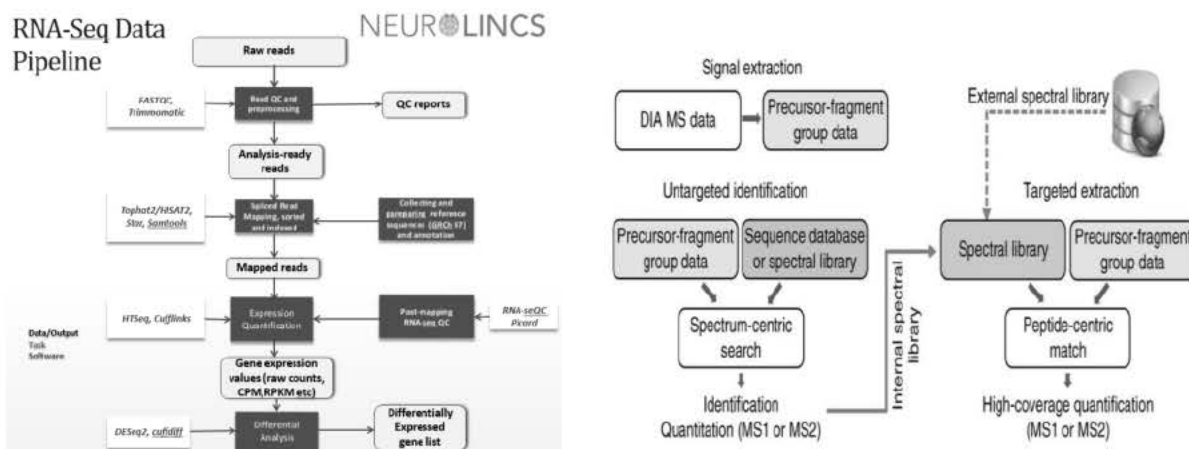
(b) (4)



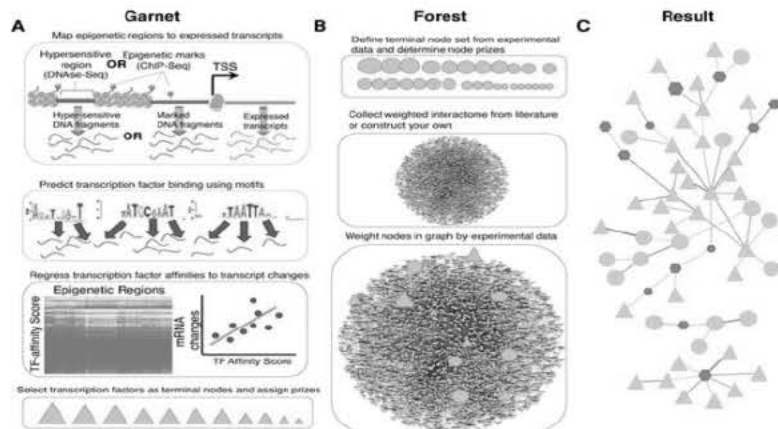


RseQC/cufflinks, IQSEQ, SamTools, iQuant, PRIDE-toolsuite, maxQuant, HTSeq, DESeq2, cuffdiff, HISATZ, FASTQC, Trimmomatic, and others. As illustrated in Figure 2, integrative analysis pipelines are also being developed by the NeuroLINCS project for combining transcriptomic, epigenomic and proteomic datasets. The vision for incorporating data analysis pipelines into the AMP-PD knowledge platform would involve NIH staff working with Verily and pipeline providers to accomplish this task. Overall, the proposed analytical pipelines to be incorporated into the AMP-PD Knowledge platform are ones that have been developed by NIH Common Fund projects or large WGS projects. These pipelines handle processing of WGS, RNA seq, epigenomic, proteomic, robotic image data, metabolomic data, and biomarker platform data. As new analytical techniques are developed NIH staff will work with Verily to bring the related analytical pipelines into the AMP-PD cloud infrastructure.

**Figure 1: NeuroLINCS pipeline for RNA Seq Analysis and DIA based proteomic analysis.** The NeuroLINCS RNA seq analysis pipeline has been published as a workflow on Galaxy Azure by Microsoft and can be executed using a graphic user interface by biologists.



**Figure 2: Omics Integrator.** The Omics Integrator applies advanced network algorithms to a network of thousands of molecular interactions to find high-confidence, interpretable subnetworks that explain the data. These subnetworks connect changes in gene expression, protein abundance or other global assays to protein that may not have been measured in the screens due to inherent bias or noise in measurements. This approach reveals unannotated molecular pathways that would not be detectable by searching pathway databases. Tuncbag N, Gosline SJ, Kedaigle A, Soltis AR, Gitter A, et al. (2016) Network-Based Interpretation of Diverse High-Throughput Datasets through the Omics Integrator Software Package. PLOS Computational Biology 12(4): e1004879.



## Cloud collaborative project management

Support would be provided for a collaborative web-based workbook/project solution that would enable a user to create and share documents that contain live code, equations, visualizations and explanatory text and that enables versioning of data files to track the analytical process. User applications could include data cleaning and transformation, numerical simulation, statistical modeling, machine learning, etc. (e.g. Jupyter, iPython, or a customized system like the Providence solution provided by SAGE).

In terms of the SAGE web-based solution for managing provenance, the concept is to expose a very general data model based on the W3C Prov spec. Central to the design is the principle that users are not required to use a particular execution environment or workflow tool. Instead, provenance can be specified by inserting calls to the synapse web service layer into the user's normal workflows to record activity, and pipelines may be created through simple scripting or by using workflow execution engines.



The provenance system allows users to branch off workflows at any point in prior analyses, while maintaining detailed records of data, code, and environment versions needed to reproduce the work.

### **Utilization of existing PDBP Data Management System Elements to support AMP-PD infrastructure**

The Parkinson's Disease Biomarkers Program Data Management Resource (PDBP DMR) has open source code available for modules that could assist searches within the cloud environment. The data dictionary contains the common data elements and unique data elements used in the form structures. Tools for account management, data uploading, and BD2K indexing are available for incorporation into the AMP-PD data knowledge platform. NINDS will maintain the PDBP DMR during the lifetime of the AMP-PD project to enable continued uploading of clinical data from ongoing Lewy Body Disease biomarker cohort studies. A PDBP DMR infrastructure architect will work with Verily to transition PDBP DMR components/modules to be used in the AMP-PD knowledge platform infrastructure. Components developed and available through the PDBP DMR for integration into the AMP-PD Knowledge platform include:

- a. Dictionary of common Data Elements
- b. Quality control of data uploads against standard form structures
  - i. Data capture, validation and submission tools, form structures for various data types
- c. Study and Protocol Definition
- d. Accounts and Group Management
- e. Dataset Discovery and Record Query Tools
- f. BD2K Indexing, DOI and Publication Management
- g. Public and Protected Sites, Branding & Content
- h. Curation of Harmonized Phenotypes
- i. Tool for Creating Synthetic Cohorts

### **NINDS DMR infrastructure elements available for integration in the AMP-PD Knowledge Platform**



ProFoRMS



GUID



Data Dictionary



Data Repository



Query



Meta Study



Account  
Management

### **Shared Data Dictionary**

The PDBP Data Management Resource (DMR) currently has 47 form structures against which data has been collected. Form structures include clinical assessments, genomic (DNA and RNA) data, immunoassay biomarker data, biosample catalog data and imaging data. The data dictionary is made up of 17,681 data elements, of which 11,667 are common data elements. The data dictionary identifies form structures using specific data elements and tracks any change history for the data element. Where

available CDISC standard references are included. This data dictionary also supports the Federal Interagency Traumatic Brain Injury Research Database.

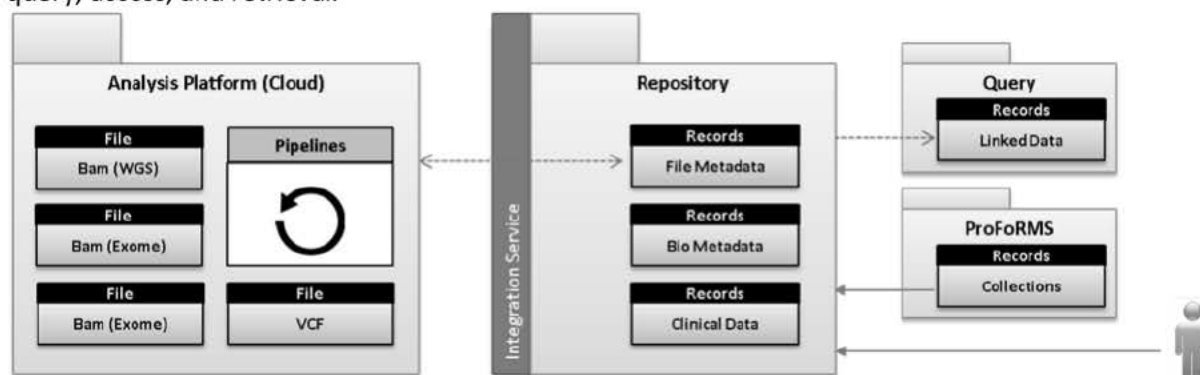
### Data Capture, Validation and Submission Tools

Currently the PDBP DMR offers a data validation and upload tool for data that is not captured and validated through the ProFoRMS module. The validation component must be used before any data can be uploaded to the data repository. The validation and submission tools run as a Java Web Start application locally on a user's computer and therefore requires the user to install the Java runtime environment. The validation component verifies that submitted data conforms to the required format and range values defined in the data Dictionary. The tool imports the Data Dictionary and validates the metadata associated with the files identified by the user for submission against the data dictionary. It provides a report of any data discrepancies and warnings. If errors are found, a submission package cannot be created. After successful creation of a submission package, data can be submitted to the system with the upload component. For imaging data, the Medical image processing, analysis and visualization (MIPAV) tool is used. This tool is also run locally on a user's computer as a Java web start application. The MIPAV tool enables users to submit unprocessed brain images in DICOM format and processed images in a variety of formats including DICOM, MINC 1.0 and 2.0, Analyze, NfTI, AFNI and SPM. The MIPAV tool creates files necessary for validation including a compressed image, a JPG file that can be used as a thumbnail to preview the image in the Query tool and a CSV file of the meta-data from the image and represents a form structure that can be queried using the Query tool. The files created for submission must be validated prior to uploading.

### Repository Access and Retrieval

AMP-PD data will be stored in the cloud. The current DMR repository provides data management tools to enable access and retrieval without physically moving the data. Users are authenticated through the DMR accounts module, and data rights assigned to AMP-PD users are verified before files may be downloaded or used as input to cloud processes including pipelines on the Analysis Platform. The DMR provides both a data transfer service to upload data to the cloud and pull data from the cloud, as well as a data access service to grant proxy access to AMP-PD data.

The Data Repository provides validation for structured data and file metadata during the submission process. All AMP-PD data must undergo the submission process, where it is validated against structural definitions in the Data Dictionary. Data can be validated in place, through a remote validation client, or through electronic submission through the repository service. Once data is validated and submitted, rights may be assigned to grant access to users, or to groups of users, or made public. All submitted data is linked to entities in the system including User, Study, Dataset, Forms and Elements that facilitate query, access, and retrieval.



File data is stored, processed, and created in the cloud. File metadata submitted to DMR describes physical location information	File metadata is submitted as a DMR dataset. DMR governs access to files by dataset and links metadata to other DMR dataset records	DMR supports data upload and submission via ProFoRMS and client tools. These data are stored in the cloud.
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### Discovery and Query Tools

The DMR today supports several types of queryable records-level data: Clinical data and BioSample, Imaging, Genomics and other file metadata. The repository also provides Study definitions and Dataset definitions with required fields sufficient to support discovery both within the system and in the broader community through the BD2K DataMed index. Studies, Datasets, Records, and Files are all identified by a URI that can be used in any application and dereferenced by authenticated users with data rights. These URI's enable linking data with concepts, with other data, with metadata, and across datasets, systems, and discovery indexes.

The DMR currently supports linked data at the record level by subject. This enables users to query clinical data from selected studies and forms, join form data, and discover rich information about subjects across forms. Each set of records for each form in query results can be filtered based on data element values and ranges defined in the Data Dictionary.

### Administrative Management of Studies and Datasets in the DMR

All datasets associated with the studies listed in the DMR can be found in the manage datasets list and can be searched by PDBP assigned administrators by keyword, ownership, or dataset status. Dataset status defines the state of the dataset and includes: 1) Private, which is the default status for all datasets until sharing of the dataset is requested; 2) Requested Deletion, a status that can be requested of private or shared datasets by the submitter. Deletion of datasets is a hard delete completed by the PDBP Admin; 3) Requested Sharing, which enables submitters to request the dataset be shared; the PDBP Admin reviews the request; 4) Requested Archive, which enables submitters to request the dataset be archived; the request is reviewed by the PDBP Admin; 5) Shared status, which indicates that the dataset is accessible to all users and cannot be modified or added to; and 6) Archived status, which indicates that the dataset will not show up by default in queries. Results of searches are provided in a tabular format.

As with datasets, all studies are listed in a content page, where users can search by keyword or status and results are shown in a tabular format. In the case of studies the status option includes: requested, public, private, rejected, or all, and defines whether the study can be viewed and data associated with the study shared with users.

### B. AMP-PD public site

The public website will support the following functions: 1) information about AMP-PD including description of data and analytical pipelines available, training videos supporting the use of the controlled access database, use case examples of data and analyses available; 2) visualization tools to assist users with data use and management; and 3) a searchable PD variant data base built from aggregate data and modeled after the UCSD genome browser.

### PD Variant Database accessible on AMP-PD public site



1. A searchable Parkinson's Variant Database will be developed on a public facing website using aggregate data from WGS analysis with overlay of data from gene expression, protein expression and epigenomic analysis. Analytical capabilities should include data quality assessment and control, preprocessing and scaling, univariate and bivariate statistics, multivariate regression, identification of differentially expressed genes, principle components analysis, unsupervised clustering, allelic association testing, and logistic regression.
2. The public facing website will also include visualization tools to assist users with data management. Visualization capabilities should include volcano plots, heat maps, and Manhattan plots. Interfaces should allow web-based specification of analyses as well as visualization and downloading of results. Tutorials involving sample data sets and analyses to illustrate use of the PD variant database analytical and visualization tools will also be included.

### **AMP-PD Knowledge Platform Proposal Options**

We envision two proposed ways in which Verily could contribute in-kind to supporting the AMP PD knowledge portal.

**Proposal A:** Verily would provide support of data storage, analysis time and infrastructure support for standardized pipeline analysis. In this scenario, once a dataset is quality controlled using a standard form structure and data dictionary, the data submitter will upload the data to the cloud environment and run a standard analysis pipeline for the specific datatype. An AMP-PD data working group will analyze pipeline data for errors prior to posting for broad user access.

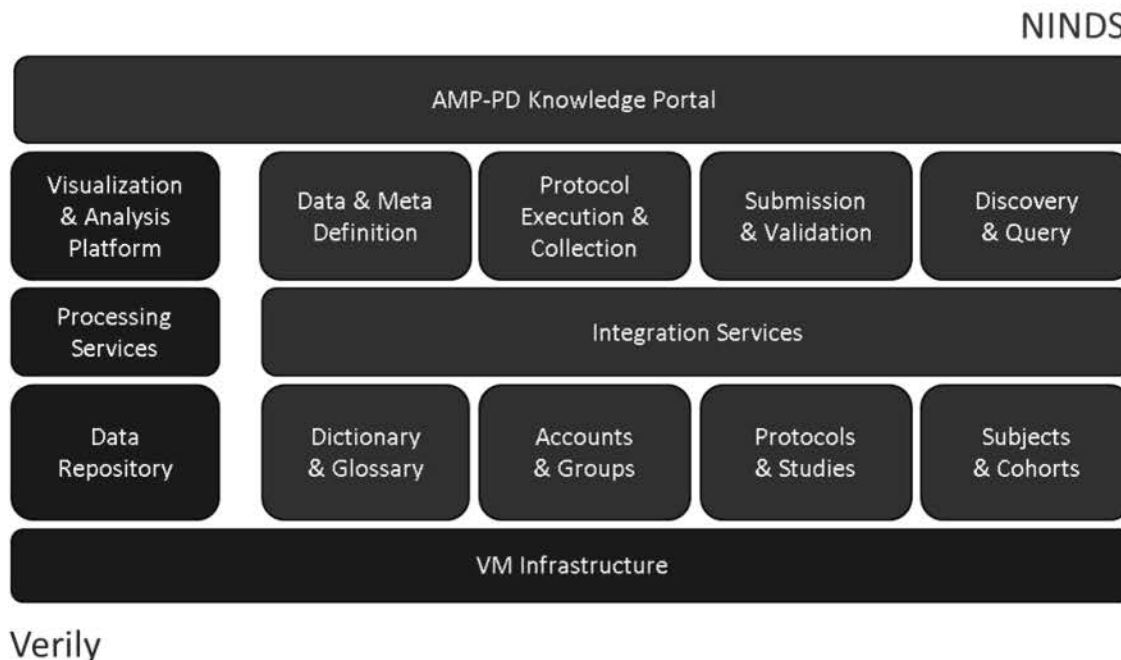
(b) (4)

**Proposal B:** Verily would provide support of data storage, analysis time and infrastructure support for standardized pipeline analysis, integration of relevant infrastructure from PDBD DMR (data dictionary, account management, data capture, validation and upload tools, query tool, harmonized cohort data), public data portal with PD variant database and visualization tools, and cloud collaborative project management.

This option would enable Verily to collaborate in building a technical platform that could be extended beyond PD to accommodate other diseases. We have not estimated commercial pricing for this option.



Figure 3: Outline of Proposal 3 indicating components from NINDS and Verily.



## References

- 1) Diagnosis of Parkinson's disease on the basis of clinical and genetic classification: a population-based modelling study. Nalls, MA et al. Lancet Neurol. 2015 Oct;14(10):1002-9. doi: 10.1016/S1474-4422(15)00178-7.
- 2) NeuroX, a fast and efficient genotyping platform for investigation of neurodegenerative diseases. Nalls, MA et al., Neurobiol Aging. 2015 Mar;36(3):1605.e7-12. doi: 10.1016/j.neurobiolaging.2014.07.028.
- 3) Large-scale meta-analysis of genome-wide association data identifies six new risk loci for Parkinson's disease. Nalls MA et al., Nat Genet. 2014 Sep;46(9):989-93. doi: 10.1038/ng.3043.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 2 Nov 2017 11:55:20 +0000  
**To:** Koroshetz, Walter (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** Re: biotech in PPP

We should discuss this in today's meeting.  
Sent from my BlackBerry 10 smartphone.

---

**From:** Koroshetz, Walter (NIH/NINDS) [E]  
**Sent:** Thursday, November 2, 2017 5:31 AM  
**To:** Baker, Rebecca (NIH/OD) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** biotech in PPP

Dear Rebecca,  
For discussion—place of smaller biotechs in the PPP?

(b) (4)

Not sure where they would fit??.

Walter

Walter J. Koroshetz, M.D.  
Director, National Institute of Neurological Disorders and Stroke

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 11 Oct 2017 18:23:31 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: BMS is in

PS, I guess we never did hear back from (b) (4) on PACT, did we?

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, October 11, 2017 1:51 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: BMS is in

I hear from Renate that Daniel Levine of BMS is being unresponsive to requests for quotes and representation at the press conference. Should I reach out to (b) (4), (b) (6)

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, October 10, 2017 10:38 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: BMS is in

Thanks, Francis, that fits the bill nicely. Working with Renate to try to get company reps to Thursday's event.

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 10, 2017 10:33 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>

**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: BMS is in

Just sent you two e-mails, that's what I have from conversations with (b) (4)

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, October 10, 2017 9:55 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** FW: BMS is in

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, July 28, 2017 7:41 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** BMS is in

(b) (4)

He was particularly glad to hear that FDA will be involved, as he thinks there is a great opportunity for precompetitive sharing of biomarker information.

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 11 Oct 2017 18:12:40 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: BMS is in

Not yet if you don't mind, he's trying. Was brought in on this last minute and is trying to coordinate across BMS. Let me try him again before you pull that trigger please.

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**Subject:** BMS is in

(b) (4)

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 10 Oct 2017 14:37:31 +0000  
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**Subject:** RE: BMS is in

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(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH)

[T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI)

[E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)

**Subject:** BMS is in

(b) (4)

He was particularly glad to hear that FDA will be involved, as he thinks there is a great opportunity for precompetitive sharing of biomarker information.

FC



**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 11 Oct 2017 19:11:19 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: BMS is in

Nor I from Joanne Lager. So it goes.

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, October 11, 2017 3:04 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Subject:** Re: BMS is in

I never heard from (b) (4)

Sent from my iPhone

On Oct 11, 2017, at 2:23 PM, Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)> wrote:

PS, I guess we never did hear back from (b) (4) on PACT, did we?

**David Wholley**  
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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, October 11, 2017 1:51 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Subject:** RE: BMS is in

I hear from Renate that Daniel Levine of BMS is being unresponsive to requests for quotes and representation at the press conference. Should I reach out to (b) (4), (b) (6)?

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, October 10, 2017 10:38 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: BMS is in

Thanks, Francis, that fits the bill nicely. Working with Renate to try to get company reps to Thursday's event.

**David Wholley**  
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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 10, 2017 10:33 AM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: BMS is in

Just sent you two e-mails, that's what I have from conversations with (b) (4).

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, October 10, 2017 9:55 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** FW: BMS is in

Hi, Francis – sorry to bother you, but I got a call this morning from a Daniel Levine at BMS who is in R&D ops and is trying to track down what is going on with PACT. I have the email regarding your phone conversation with (b) (4), (b) (6), but would you happen to have received any communication in writing from (b) (4), (b) (6) regarding their decision to join PACT? Not a big deal, but might be helpful to Dan if you could pass along anything to me that floats up on an email search. Thanks, David

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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, July 28, 2017 7:41 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]  
(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH)  
[T] <sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI)  
[E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** BMS is in

(b) (4)

He was particularly glad to hear that FDA will be involved, as he thinks there is a great opportunity for precompetitive sharing of biomarker information.

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 9 Mar 2017 15:42:38 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Bristol-Myers replaces CSO at key point for pipeline

Thanks for sending this on Francis. Indeed. Well, I think technically we have to offer Francis's spot to another R&D head, and that is an opportunity. (b) (5)  
I think getting Mikael's and Jan's views on whom to approach would be a good first place to start. (b) (5)

Please let me know your thoughts.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, March 09, 2017 3:32 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** FW: Bristol-Myers replaces CSO at key point for pipeline

Oh no!

---

**From:** Austin, Christopher (NIH/NCATS) [E]  
**Sent:** Thursday, March 09, 2017 1:05 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Bristol-Myers replaces CSO at key point for pipeline

Hi Francis,

This is quite incredible news. (b) (5)  
(b) (5) (b) (6) (b) (6)

I wonder if Tom will be at Hever?

Chris

# Bristol-Myers replaces CSO at key point for pipeline

---

by *Nick Paul Taylor* |  
Mar 9, 2017 8:42am

*Lynch inherits a pipeline featuring 21 oncology programs*

Bristol-Myers Squibb has **appointed** Thomas Lynch to replace Francis Cuss as CSO. The reshuffle puts the former CEO of Massachusetts General Physicians Organization in charge of returning the luster to Bristol-Myers' R&D pipeline after a period in which setbacks to Opdivo have dampened expectations.

Lynch joins Bristol-Myers following a 12-month period in which the company's share price fell by close to 12%. If Bristol-Myers is to make up lost ground, both on the stock market and in the immuno-oncology space, Lynch will need to wrangle the company's 21-program clinical cancer pipeline into products and combinations that outperform those developed by Merck, Roche and the rest of the congested field.

In Lynch, Bristol-Myers has gained an executive with extensive experience treating and researching cancer from spells at Yale Cancer Center and Massachusetts General Hospital, where he was part of a team that linked genetic mutations to treatment response in lung cancer patients.

With Bristol-Myers coming off the back of a phase 3 that blew up after targeting a broad patient population, rather than limiting enrollment to heavy-expressors of PD-L1, Lynch's track record of looking at which lung cancer patients are likely to respond could stand him in good stead. That is the hope at Bristol-Myers.

"We are confident Tom is the right person to lead our dynamic R&D organization as we focus on accelerating the development of our immuno-oncology medicines and fully realizing the extraordinary potential of our diverse, innovative pipeline. With deep experience as a clinical researcher, leader of large research centers and a practicing physician, Tom brings unique, important and timely perspectives to the business," Bristol-Myers CEO Giovanni Caforio, M.D. said in a statement.

The rejig signals the end of Cuss' 14-year stint at Bristol-Myers. Starting out as SVP of drug discovery, Cuss oversaw a period in which Bristol-Myers became known for having one of the less dysfunctional R&D operations among its peer group. Then, upon taking over as CSO in 2013, Cuss moved Bristol-Myers out of metabolic, neuroscience and virology drug discovery, resulting in the company hitching its future to immuno-oncology and specialty diseases.

Cuss' reasoning that Bristol-Myers had already lost the hepatitis C market and that neuroscience would remain a money pit has held up. And his belief in immuno-oncology

and specialty diseases has been validated, too, although the recent missteps in the development of Opdivo mean other companies may profit more from the growth of the former than Bristol-Myers.

Responsibility for ensuring Bristol-Myers delivers drugs that capture a sizable slice of the market will now fall on Lynch. In addition to the 21 oncology programs, Lynch inherits a pipeline with multiple shots on goal in the cardiovascular space, fibrotic diseases and, in particular, immunoscience. But, with Bristol-Myers in the middle of another R&D reorganization and activist investor Carl Icahn buying up some of its stock, he also joins at a time of upheaval and pressure.

Christopher P. Austin, M.D.

Director

National Center for Advancing Translational Sciences

National Institutes of Health

<http://ncats.nih.gov>



***NIH NCATS: Improving Health Through Smarter Science***

***Connect with us!:*** <https://ncats.nih.gov/connect>



**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 10 Mar 2017 12:06:34 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Bristol-Myers replaces CSO at key point for pipeline

Sure, sounds good. Do you want me to reach out to Jan or would you prefer to handle that?  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, March 10, 2017 5:37 AM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** RE: Bristol-Myers replaces CSO at key point for pipeline

Yes, let's consult with Mikael and Jan.

I have a phone call with Mikael next Monday, how about I ask his advice then?

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thursday, March 09, 2017 3:43 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Bristol-Myers replaces CSO at key point for pipeline

Thanks for sending this on Francis. Indeed. Well, I think technically we have to offer Francis's spot to another R&D head, and that is an opportunity. (b) (5)  
I think getting Mikael's and Jan's views on whom to approach would be a good first place to start. (b) (5)

Please let me know your thoughts.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, March 09, 2017 3:32 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** FW: Bristol-Myers replaces CSO at key point for pipeline

Oh no!

---

**From:** Austin, Christopher (NIH/NCATS) [E]  
**Sent:** Thursday, March 09, 2017 1:05 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Bristol-Myers replaces CSO at key point for pipeline

---

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This is quite incredible news.

(b) (5)

(b) (6)

(b) (6)

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## Bristol-Myers replaces CSO at key point for pipeline

---

by Nick Paul Taylor |  
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In Lynch, Bristol-Myers has gained an executive with extensive experience treating and researching cancer from spells at Yale Cancer Center and Massachusetts General Hospital, where he was part of a team that linked genetic mutations to treatment response in lung cancer patients.

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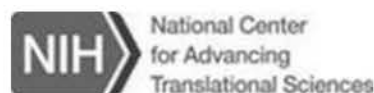
realizing the extraordinary potential of our diverse, innovative pipeline. With deep experience as a clinical researcher, leader of large research centers and a practicing physician, Tom brings unique, important and timely perspectives to the business,” Bristol-Myers CEO Giovanni Caforio, M.D. said in a statement.

The rejig signals the end of Cuss’ 14-year stint at Bristol-Myers. Starting out as SVP of drug discovery, Cuss oversaw a period in which Bristol-Myers became known for having one of the less dysfunctional R&D operations among its peer group. Then, upon taking over as CSO in 2013, Cuss moved Bristol-Myers out of metabolic, neuroscience and virology drug discovery, resulting in the company hitching its future to immuno-oncology and specialty diseases.

Cuss’ reasoning that Bristol-Myers had already lost the hepatitis C market and that neuroscience would remain a money pit has held up. And his belief in immuno-oncology and specialty diseases has been validated, too, although the recent missteps in the development of Opdivo mean other companies may profit more from the growth of the former than Bristol-Myers.

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Christopher P. Austin, M.D.  
Director  
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***Connect with us!:*** <https://ncats.nih.gov/connect>

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 16 Oct 2017 14:23:32 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: can you call in at noon?

Sorry, Francis I am in a meeting with our Board until 3. I can follow up at that time or later.  
David

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, October 16, 2017 10:14 AM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** can you call in at noon?

I understand you might have a conflict with FNIH Board, but can you call in at noon for the opioid team meeting?

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 8 Dec 2017 21:14:55 +0000  
**To:** Flores, Christopher [CONUS]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Can you co-lead the final meeting summary session next week with Francis Collins?

Great!! We (you, Francis, us) can huddle sometime after the end of day 1 festivities to take stock and figure out how to work this out. Thanks so much for all your helpful involvement in our efforts so far—they've really made a difference.

---

**From:** Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]  
**Sent:** Friday, December 8, 2017 3:45 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Francis Collins (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: Can you co-lead the final meeting summary session next week with Francis Collins?

Happy to, David.

See you all next week,  
Chris

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]  
**Sent:** Friday, December 08, 2017 3:34 PM  
**To:** Flores, Christopher [CONUS] <CFlores2@its.jnj.com>  
**Cc:** Francis Collins (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** Can you co-lead the final meeting summary session next week with Francis Collins?

Dear Chris,  
In going over the final meeting agenda for next week's meeting on the opioids partnership with Francis Collins he asked if you might co-lead with him the final talk summarizing the major findings and action items of the two days on the afternoon of Dec. 13. We (FNIH) would summarize major points on powerpoint as we go along and have that available to you both after the final break to support your joint presentation and any ensuing discussion. Can you please let us know as soon as possible if you'd be willing to do this?

Thanks,  
David Wholley

Sent from my BlackBerry 10 smartphone.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 20 Nov 2017 19:33:43 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]  
**Subject:** RE: Conversation with industry participants from both focus areas: week of Dec 4?

Hi Francis,  
We had already agreed to such a call – it is on the revised workgroup meeting schedule I sent for last week's check-in call. Plan is to get the co-chairs' schedules first and invite anyone else who wants to join from there. Right now we are looking at Dec 6, 7, or 8. Will let you know soon as we have some more availability data.  
David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, November 20, 2017 12:19 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)  
**Subject:** Conversation with industry participants from both focus areas: week of Dec 4?

Hi David,

I understand that the consultation process is now underway with the three working groups in the pain focus area, and things are off to an excellent start. Thank you for all the work of your team to get these groups off the ground.

I am also thinking hard about December 11, when it will be important to present a cohesive whole about the partnership for the PhRMA Board meeting, especially since we hope this will be an occasion where the CEOs might be willing to make some financial commitments.

Would it be possible to convene the industry reps (or at least the co-chairs?) for both project 1 and project 2 by teleconference during the week of December 4, in order to prepare optimally for the PhRMA presentation on December 11?

Please let me know what you think.

Thanks, Francis



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 20 Nov 2017 20:31:41 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]  
**Subject:** RE: Conversation with industry participants from both focus areas: week of Dec 4?

PS, we are working around it but the biggest challenge seems to be some kind of NIH pain meeting on the 8<sup>th</sup> and 9<sup>th</sup>...

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, November 20, 2017 2:59 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] <porterl@ninds.nih.gov>  
**Subject:** RE: Conversation with industry participants from both focus areas: week of Dec 4?

Great, thanks!

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, November 20, 2017 2:34 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)  
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**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]



(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)

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I am also thinking hard about December 11, when it will be important to present a cohesive whole about the partnership for the PhRMA Board meeting, especially since we hope this will be an occasion where the CEOs might be willing to make some financial commitments.

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Please let me know what you think.

Thanks, Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 23 Oct 2017 11:40:24 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Draft of slides for discussion on tomorrow's AMP EC pre-call

We know! The usual challenge  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, October 22, 2017 9:23 PM  
**To:** Wholley, David (FNIH) [T]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]  
**Cc:** Hoffmann, Steve (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Vardanian, Lilit (FNIH) [T]; Canet-Aviles, Rosa (FNIH) [T]; Cush, Stephanie (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Morgan, Emily (FNIH) [T]  
**Subject:** RE: Draft of slides for discussion on tomorrow's AMP EC pre-call

Looking forward to discussing tomorrow. Presentations may need to be trimmed a bit to allow discussion on Friday.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sunday, October 22, 2017 8:51 PM  
**To:** McManus, Ayanna (NIH/OD) [E]; (b) (6) Wood, Gretchen (NIH/OD) [E]; (b) (6) Boskent, Celeste (NIH/OD) [E]; (b) (6) Di Mantova, Emma (NIH/OD) [E]; (b) (6); Collins, Francis (NIH/OD) [E]; (b) (6)  
**Cc:** Hoffmann, Steve (FNIH) [T] <shoffmann@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Vardanian, Lilit (FNIH) [T] <lvardanian@fnih.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Cush, Stephanie (FNIH) [T] <scush@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>  
**Subject:** Draft of slides for discussion on tomorrow's AMP EC pre-call  
**Importance:** High

This is what I have so far for tomorrow's call. Still awaiting review/inputs from some of the co-chairs. Look forward to our discussion.

(b) (6) Expect I will be able to call in and moderate the EC call, but if for any reason I am unable to (it will be 6AM where I am, and not a familiar environment) Joe Menetski is prepared to lead the call from the FNIH side without me.

Thanks, David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 17 Oct 2017 15:59:09 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Allen-Gifford, Patrice (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** RE: email drafts for opioids partnership

Great. Rebecca said she would work with your calendar. I will try to work my schedule around whatever is selected.

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 17, 2017 6:56 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Allen-Gifford, Patrice (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** RE: email drafts for opioids partnership

Hi David,

These drafts all look great to me. As I am out of pocket, I am asking Rebecca to work with Gretchen and/or Exec Sec to get these sent out from my e-mail today. We need to nail down the time for the 90 minute Friday call right away. To be nice to those in Europe or the west coast, an 11 AM call might be best.

FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, October 17, 2017 12:29 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>  
**Subject:** email drafts for opioids partnership

Francis,

Here are the emails I have composed for

1. (b) (5), the lead industry co-chair identified by Walter and Linda for Focus Area #2. Note that we are still waiting to see if Nora wants an industry co-chair for area #1.
2. Invitation to all industry reps to participate in the partnership generally and the Friday call specifically. Note you may need to adjust how logistics info for the call is handled—I think we will need Rebecca's help here. The note would be sent to the attendees on the lists provided to Rebecca by Bill Chin.
3. An invitation to academic invitees to work on focus area #2 who attended one of the NIH workshops over the summer. Again, we would need to see Nora's plan and whether she wants such invitees for focus area 1 before proceeding.
4. An invitation to academic invitees to work on focus area #2 who did NOT attend any of the NIH workshops and are newer to the process.

The academic invitees for notes 3 and 4 are:

(b) (5)

We are working to find their email addresses, but I am copying Linda Porter to see if she can provide them faster. Linda, I assume Francis should start with Tor (b) (5), and then based on the outcome of Friday's call we can invite (b) (5)

Thanks, David

David Wholley  
Director, Research Partnerships  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Sat, 8 Apr 2017 10:58:18 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Emailing - Technical Plan for AMP PD knowledge portal.pdf

Tech plan may include some proposal 1 stuff, sorry. Go with what Marg says.  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Saturday, April 8, 2017 10:49 AM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]; Sutherland, Margaret (NIH/NINDS) [E]  
**Subject:** RE: Emailing - Technical Plan for AMP PD knowledge portal.pdf

Got it, thanks

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Saturday, April 08, 2017 10:49 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnih.org>; Sutherland, Margaret (NIH/NINDS) [E] (b) (6)  
**Subject:** Emailing - Technical Plan for AMP PD knowledge portal.pdf

Francis: This is the technical plan we shared with Verily. It is a little hard to tease out but it seems the core databases (PPMI, Harvard Biomarker Study, PDPB) total today about 3500 cases and 6000 controls. I have asked Rosa Canet-Aviles and Marg Sutherland to weigh in directly on this in the interest of time.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 20 Dec 2017 13:53:56 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]  
**Subject:** RE: FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Thanks, Rebecca. If I may add one thing, it would be just a reminder that PhRMA wants this one kept very brief. The original suggested length was two pages, and we're over that already. So if you want to insert something of any length, I would ask that you show where something of corresponding length should be taken out. Also, it would be helpful if you could make your suggested changes as redlines rather than general comments. Thanks, David

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Wednesday, December 20, 2017 8:39 AM  
**To:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] <jack.stein@nih.gov>  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>  
**Subject:** FAST TURNAROUND REVIEW: Opioid PPP update for BMAC 12-19-17 draft for NIH

Good morning,

As follow up to last week's partnership design meeting, FNIH has drafted the attached summary to share with the PhRMA Biomedical Advisory Council.

PhRMA has asked for a draft by COB today. Could you please review and send your revisions and edits by 4 PM today? Please be sure to copy David and Mike.

Thank in advance for your thoughts,

Rebecca

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, December 19, 2017 7:38 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>  
**Subject:** Opioid PPP update for BMAC 12-19-17 draft for NIH

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his

introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 27 Nov 2017 21:47:50 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** Re: FDA Meeting on December 11-12

Ok, thanks.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, November 27, 2017 1:46 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Porter, Linda (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: FDA Meeting on December 11-12

That's fine as long as you are sure we will have good representation from the companies involved in focus area 1 on the morning of the 12<sup>th</sup>.

FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, November 27, 2017 11:53 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** FW: FDA Meeting on December 11-12

Please see below. I think we stick to our original plan of kicking this off with focus area 1 on the morning of day 1 (12<sup>th</sup>), then going to pain on that afternoon of day 1 and continuing the discussion the following day (13<sup>th</sup>). We can include the key conclusions from focus area 1 discussion in the sum-up at the end of day 2 (of course). Let me know what you think.

---

**From:** Hertz, Sharon H (b) (6)  
**Sent:** Monday, November 27, 2017 11:30 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** RE: FDA Meeting on December 11-12

Thanks, that is a great idea except Ellen will be covering the division while I am at the FDA meeting. I understand that it is difficult to move meetings with so many people.

I don't think you need to change the agenda for the meeting. Both areas are important, so I'll just have to miss whichever is on the 12<sup>th</sup>.

Sharon

Sharon Hertz, MD  
Division Director  
DAAAP  
(b) (6)

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]  
**Sent:** Monday, November 27, 2017 11:18 AM  
**To:** Hertz, Sharon H (b) (6)  
**Cc:** Biarnes, Michael C (NIH) <mbiarnes@fnihi.org>; Menetski, Joseph M (NIH) <jmenetski@fnihi.org>  
**Subject:** RE: FDA Meeting on December 11-12

What if we did pain on the 12<sup>th</sup> and delayed focus area 1 (addiction and overdose) discussions to the morning of day 2 (the 13<sup>th</sup>). Am assuming someone like Ellen Fields might be able to make both the 12<sup>th</sup> and 13<sup>th</sup>, and provide some continuity. Would that work?

---

**From:** Hertz, Sharon H (b) (6)  
**Sent:** Monday, November 27, 2017 9:17 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Biarnes, Michael (FNIH) [T] <mbiarnes@fnihi.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>  
**Subject:** RE: FDA Meeting on December 11-12

It is some of the companies. I don't know if it is the same people or not, but there are many issues that could impact the drug and device companies so we expect many to attend. Beyond that, many of us at FDA are conflicted. For example, Doug Throckmorton and I are speaking/moderating on the 12<sup>th</sup>. We can have people cover, but I'm sure you understand that it is very difficult to have continuity from us if different people attend meetings on the same topic.

Sharon

Sharon Hertz, MD  
Division Director  
DAAAP  
(b) (6)

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]  
**Sent:** Sunday, November 26, 2017 1:09 PM  
**To:** Hertz, Sharon H (b) (6)



**Cc:** Biarnes, Michael C (NIH) <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Menetski, Joseph M (NIH) <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>  
**Subject:** FDA Meeting on December 11-12

Hi Sharon—

On one of our opioid partnership calls last week you brought up a concern that our face to face meeting scheduled for December 12-13 will conflict with a meeting FDA is planning to hold on Dec 11-12. I did speak to NIH leadership about this and they are concerned there are other conflicts, making moving the dates of the 12-13<sup>th</sup> meeting. In looking up the FDA meeting on the Federal Register, I notice it is specifically to discuss Packaging, Storing, and Disposal Options to Enhance Opioid Safety. Given this I am not sure of the degree of overlap with our planned meeting. I can see where some of the same companies would attend both meetings, but do you anticipate it will be the same actual personnel from those companies? And would the conflicts apply equally to the representatives and companies attending the current pain focus area discussions, or is it mainly a concern with respect to the companies associated with the addiction and overdose focus area currently led by NIDA? If the latter, though not optimal we could consider arranging the agenda for the 12-13 to put the addiction and overdose discussions on the second day. Please let me know. David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 26 Feb 2017 22:14:48 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Wood, Gretchen (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; NIHDirectorMeetings; Adam, Stacey (FNIH) [T]  
**Subject:** Re: Final draft of PACT white paper

Thanks Francis. We do too.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, February 26, 2017 10:05 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Wood, Gretchen (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; NIHDirectorMeetings; Adam, Stacey (FNIH) [T]  
**Subject:** RE: Final draft of PACT white paper

Hi David,

I wasn't able to read every word of the PACT summary, but what I saw looked very good. So for now I have no changes to suggest. I'm hoping for a strongly positive response from the companies.

Francis

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, February 24, 2017 4:55 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** FW: Final draft of PACT white paper

Hi Francis:

I just wanted to remind you that we'd sent you the final draft PACT document for review and ask that if you have any changes to suggest you get them back to Stacey and me by Monday noon. We want to keep our promise to get this final version officially "out" to the companies in February. Thanks, David

---

**From:** Adam, Stacey (FNIH) [T]  
**Sent:** Monday, February 20, 2017 5:12 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
Lowy, Douglas (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Abrams, Jeff (NIH/NCI) [E] (b) (6)  
**Cc:** Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Lea, Allison (NIH/OD) [E] (b) (6)  
**Subject:** RE: Final draft of PACT white paper

Dear NIH and NCI Colleagues,

As promised in my email last night, I am circulating a new draft of the whitepaper with a number of edits made.

Again, if you have already started your review on the other draft we sent, that is no problem. I will be able to still incorporate your edits into this new draft. If you have not yet started your review, I would recommend reviewing this new draft.

Please do not hesitate to reach out if you have any questions. We look forward to receiving your feedback early this week.

Thank you again for your assistance in this effort.  
Stacey

**Stacey J. Adam, Ph.D.**  
Scientific Program Manager, Cancer  
Foundation for the National Institutes of Health  
Direct (301) 435-8364 | Mobile (b) (6)

---

**From:** Adam, Stacey (FNIH) [T]  
**Sent:** Sunday, February 19, 2017 9:21 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
Lowy, Douglas (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]  
(b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Abrams, Jeff  
(NIH/NCI) [E] (b) (6)>  
**Cc:** Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>  
**Subject:** RE: Final draft of PACT white paper

Dear NIH and NCI Colleagues,

I hope you all are having a lovely long weekend and you are getting some well-earned rest. I wanted to reach out and remind you that the draft we provided last week for the PACT whitepaper was to be copy edited and one-voiced simultaneously with your review.

To that end, if you have begun reviewing the draft that was sent, I would ask that you not spend a lot of time on wordsmithing as we have just received copy edits from our writing team and they have done quite a thorough review. However, if you have not begun review of the draft yet, and would like to hold off, I should be circulating a new draft tomorrow with all of their revisions and a others that I have received.

No matter which draft you review, I will be sure to incorporate you suggested changes. We appreciate you taking the time to review the draft and provide us with any feedback that you may have.

Thanks,  
Stacey

**Stacey J. Adam, Ph.D.**  
Scientific Program Manager, Cancer  
Foundation for the National Institutes of Health  
Direct (301) 435-8364 | Mobile (b) (6)

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Monday, February 13, 2017 9:47 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E]  
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Doroshow, James  
(NIH/NCI) [E] (b) (6); Abrams, Jeff (NIH/NCI) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>  
**Subject:** Final draft of PACT white paper

Dear Francis, Doug, Larry, Jim, and Jeff,

I hope this note finds you all well. As promised, I am sending you the final draft of the PACT white paper for your review. It is still going through a final copy edit and layout, but has been fully reviewed and vetted by our NCI, FDA, and company PACT team members; all of them agree this version of the document reflects the consensus of the group and is ready for circulation to you.

I would ask that you please return any final feedback or edits you may have to Stacey Adam and me by COB Thursday (February 16) if possible. Because the final formatting of the document is being done simultaneously with your review, we should be able to incorporate any final edits swiftly. Our goal is to get the final document to the companies and other stakeholders by the end of this week if possible so we can begin formal fundraising. I have also attached again the list of companies we intend to approach; we have already confirmed the names of the appropriate contacts for this outreach with the company members who participated in the design effort. We have also already spoken with some of the other potential partners, including the Parker Foundation, Friends of Cancer Research, and Cancer Research Institute, and will follow up with others concurrent with the company discussions. So far, all of the discussions have been pretty positive.

Thank you all for the time and the support you have provided to us during this process and for the excellent work your teams have contributed to the draft alongside our company and academic partners. Please let me know if there is anything you'd like to discuss further upon reviewing this. I will be in Houston for the AMP RA/SLE meeting beginning Wednesday, but can make myself available by phone if needed.

Thanks,  
David



**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 28 Feb 2017 21:46:17 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Final draft of PACT white paper

Sure, Francis, happy to talk about this. Shall I have Cheryl set up a time?

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, February 28, 2017 8:16 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** FW: Final draft of PACT white paper  
**Importance:** High

Hi David,

Sometime we should have a conversation about the occasions where my speeches team requests FNIH materials for my presentations. The formatting of ppt slides tends to make these unusable for my projection purposes, and there seems to be more friction than necessary here. Is there someone at FNIH who helps with this, or does this all fall on your shoulders?

Not urgent, but sometime.

FC

---

**From:** Burklow, John (NIH/OD) [E]  
**Sent:** Tuesday, February 28, 2017 6:23 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Pelis, Kim (NIH/OD) [E] (b) (6)  
George, Jill (NIH/OD) [E] (b) (6); Kolberg, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** FW: Final draft of PACT white paper  
**Importance:** High

Hi, Francis—

Here are the outreach slides from David.

Hope you feel better soon!

John

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, February 28, 2017 5:05 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; George, Jill (NIH/OD) [E] (b) (6); Pelis, Kim (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6)

**Subject:** RE: Final draft of PACT white paper  
**Importance:** High

All--Here are the slides requested. Not sure if you need the slides with the names of all the NIH and FDA participants or whether that belongs in backup. Up to you/Francis of course. Good luck tomorrow.  
David Wholley

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Tuesday, February 28, 2017 10:49 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fni.h.org>  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fni.h.org>; George, Jill (NIH/OD) [E] (b) (6); Pelis, Kim (NIH/OD) [E] (b) (6)  
**Subject:** Re: Final draft of PACT white paper

Thanks,

I'm out of the office. Could you please provide the roll-out plan, including dates for each group with whom we'll be sharing the wp, to the presentations group copied here?

Dr. Collins asked for this information in preparation for his meeting with Mikael Dolsten tomorrow.

Could you please send by COB?

Thanks,  
Rebecca

Sent from my iPhone

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 6 Apr 2017 15:51:15 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Final notes for HEVER

Great!

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, April 06, 2017 3:49 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: Final notes for HEVER

Thanks, David.

BTW, I spoke with Patrick Vallance today about a PPP on non-addictive pain meds, and he was very positive – especially about the biomarker part. He will speak in favor of this on Saturday.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thursday, April 06, 2017 3:15 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) Doroshov, James (NIH/NCI) [E]  
(b) (6)  
**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6)  
**Subject:** Final notes for HEVER  
**Importance:** High

Hi Francis and Jim:

Here is the revised final status grid for PACT, updated to reflect my and Stacey's conversation with Mike Severino and Tom Hudson this morning (put them in the plus column). You had also asked for a copy of our "crib notes" from our meetings with the companies—these are now also fully updated and attached. Since our conversations with these folks were tacitly confidential, please treat with appropriate discretion.

With this, and my reply to Francis's email about the HEVER "respondent" questions sent last night, you should have everything you need. I will let you know any late breaking information by email. I will also check my Blackberry over the weekend from time to time; you can also reach me on my cell at (b) (6) if anything comes up. Good luck, and let us know anything else we can do to support you.

David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 24 Feb 2017 09:04:20 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: follow up

Thanks. Francis Cuss was on the call—he announced himself before you got on.

(b) (4)

OK?  
David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, February 24, 2017 8:30 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** follow up

Good call today. Was Francis Cuss not on the call?

(b) (4) Would it be  
useful for me to reach out personally to him?

FC



**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 27 Feb 2017 12:47:47 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: follow up  
**Attachments:** AMP PD (b) (4) Proposal dwrev.docx

Francis--I just heard back from (b) (4). She said they are pursuing internally and (b) (4) is aware, but she has no particular preference as to whether you contact him or not. Which means it would be fine if you did. FYI here is a copy of the revised proposal for funding I sent (b) (4) several weeks ago. Of course please let me know if you need anything else from me.

Thanks, David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, February 24, 2017 9:47 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** RE: follow up

Sounds good, please ask her.

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, February 24, 2017 9:04 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: follow up

Thanks. Francis Cuss was on the call—he announced himself before you got on.

OK?  
David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, February 24, 2017 8:30 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** follow up

Good call today. Was Francis Cuss not on the call?

(b) (4) Would it be  
useful for me to reach out personally to him?

FC

Accelerating Medicines Partnership Parkinson's Disease Initiative Update  
2/8/2017

The Accelerating Medicine Partnership (AMP) in Parkinson's Disease (PD) is a proposed partnership between the National Institutes of Health, industry partners and non-government organizations with the goals of executing innovative research that advances the identification and validation of new therapeutic targets for drug development and developing biomarkers that will support better clinical trial designs in PD.

In August 2016 an AMP-PD Technical Working Group was convened and tasked with drafting a white paper that represented the first stage of a consensus research plan on the key challenges the initiative should address (attached as a supplement). The original plan considered a broader scope that included two projects; 1) Target and Assays, which would identify and validate putative new therapeutic targets for PD based on genetics, and 2) Clinical Biomarkers to enable Proof-of-Concept (POC) Trials, which would focus on the validation of clinical biomarkers to be used in phase 2 POC trials. **After thorough review by all partners, a decision was made to move forward, at present, with Project 2 only as part of the AMP PD program.**

As stated in the AMP PD white paper, Project 2 takes advantage of already existing exceptional, clinically phenotyped, longitudinal genetically characterized PD cohorts with extensive, state-of-the-art linked longitudinal biobanks (*PPMI, PDBP, Harvard Biomarkers Study, PARS, and others*). Additionally, AMP PD is designed with a key element to provide the interface for data access and analysis for AMP PD investigators and the larger research community; the AMP-PD Knowledge Platform. As further detailed in the white paper AMP PD is designed as a five-year effort, with launch currently projected for 3Q 2017.

(b) (4)

Details on these are described in the white paper beginning on page 23.

FNIH has now confirmed a total of (b) (4) over five years from four private sector partners (GSK, MJFF, Pfizer, and Verily, (b) (4)). A key design point of AMP is funding equity among private sector partners. (b) (4)

(b) (4) with the first year's payment requested by mid-year 2017.

(b) (4)

This will enable a number of the already identified buy-ups to be funded. The selection of which buy-ups to prioritize, as well as other aspects of the final research plan (e.g., exact project logistics and budget allocations, start dates, timelines, and milestones) will be decided by representatives of the committed private sector partners and NIH in a face to face meeting to be convened by FNIH

(b) (4)



**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 28 Apr 2017 09:33:03 -0400  
**To:** Lowy, Douglas (NIH/NCI) [E]; Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** Re: Follow-up to Request for PACT Funding

Thanks, Doug. Agree.

David

Sent from my BlackBerry 10 smartphone.

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Friday, April 28, 2017 8:25 AM  
**To:** Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Doroshow, James (NIH/NCI) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** Re: Follow-up to Request for PACT Funding

David,

Jim and I concur that what you have written is excellent. (b) (5)

(b) (5)

Thanks,  
Doug

---

**From:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Date:** Thursday, April 27, 2017 at 6:12 AM  
**To:** "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Lowy, Douglas" (b) (6),  
"Doroshow, James (NIH/NCI) [E]" (b) (6)  
**Cc:** "Baker, Rebecca (NIH/OD) [E]" (b) (6) "Adam, Stacey (FNIH) [T]" <sadam@fnih.org>,  
"Tabak, Lawrence (NIH/OD) [E]" (b) (6)  
**Subject:** RE: Follow-up to Request for PACT Funding

Excellent response, David. I'll be interested in Jim's view, but I think it would be fine to send this to Mikael.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, April 26, 2017 8:02 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** FW: Follow-up to Request for PACT Funding

Francis, Doug, and Jim:

As promised I got the follow-up notes out today, and below is Mikael Dolsten's response. As you can see, he is still onto his idea expressed several weeks back of breaking PACT into optional modules that different pharma could bid on separately. (b) (5)

Hi Mikael:

Thanks for your insights and suggestions. The PACT plan is in fact already somewhat modular, although given that PACT is a partnership in one disease area with a fairly unitary focus it is not quite the same as AMP, where we ended up addressing a general area of R&D challenge (target identification and validation) across three very different disease areas using what turned out to be in fact 3-4 pretty distinct scientific approaches.

To answer your question, our sense on one hand is that there are three "modules" in PACT, as follows, with approximate current estimated cost:

(b) (5)

Module 3 seems clearly separable from the first two, particularly the co-funding of clinical trials, which could potentially be handled outside PACT on a case by case basis if cost is a concern. On the other hand, separating modules 1 and 2 would be substantially more problematic. Almost all of the 14 companies involved in the design felt that the new biomarker piece (module 2) is where the most value lies, but that this value would very difficult if not impossible to realize without also investing substantially in the underlying infrastructure (module

(b) (5)

(b) (5)

(b) (5)

Regards,  
David



---

**From:** Dolsten, Mikael [<mailto:Mikael.Dolsten@pfizer.com>]  
**Sent:** Wednesday, April 26, 2017 4:35 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>  
**Cc:** Abraham, Robert <[Robert.Abraham@pfizer.com](mailto:Robert.Abraham@pfizer.com)>; Rejto, Paul <[paul.rejto@pfizer.com](mailto:paul.rejto@pfizer.com)>; Adam, Stacey (FNIH) [T] <[sadam@fnihi.org](mailto:sadam@fnihi.org)>; Donnelly, Meredith (FNIH) [T] <[mdonnelly@fnihi.org](mailto:mdonnelly@fnihi.org)>  
**Subject:** Re: Follow-up to Request for PACT Funding

David

I think we expressed at HEVER a preference to consider to participate in specific sub-modules , similar to AMP, rather than entire program . This would offer more alignment w our focus and also mitigate funding levels pending breadth of your interest

Do you foresee PACT able to delineate 2-3 modules ?

Sent from my iPhone

On Apr 26, 2017, at 4:18 PM, Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)> wrote:

Dear Bob, Paul, and Mikael,

We are reaching out to follow-up on the PACT Initiative funding request detailed in the email chain below. We know that Mikael attended the HEVER meeting where PACT was discussed, and have heard that overall reception of the effort at HEVER was very positive. We understand that companies have requested some time to discuss the outcome of the meeting internally, but just wanted to follow up to see if you have any further questions and to understand your view of the next steps in the process for Pfizer.

If you would like to meet to discuss, please let Stacey Adam ([sadam@fnihi.org](mailto:sadam@fnihi.org)) know with whom we should work to get something scheduled.

Please also let us know if you have any questions that you need addressed prior to the call, and we will be glad to answer as best we can via email.

Thanks,

David Wholley and Stacey Adam

---

**From:** Melencio, Cheryl (FNIH) [T] **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, March 22, 2017 11:36 AM  
**To:** 'robert.abraham@pfizer.com' <[robert.abraham@pfizer.com](mailto:robert.abraham@pfizer.com)>; 'paul.rejto@pfizer.com' <[paul.rejto@pfizer.com](mailto:paul.rejto@pfizer.com)>; Dolsten, Mikael <[mikael.dolsten@pfizer.com](mailto:mikael.dolsten@pfizer.com)>  
**Cc:** Adam, Stacey (FNIH) [T] <[sadam@fnihi.org](mailto:sadam@fnihi.org)>; Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Donnelly, Meredith (FNIH) [T] <[mdonnelly@fnihi.org](mailto:mdonnelly@fnihi.org)>  
**Subject:** FW: Partnership for Accelerating Cancer Therapies (PACT) - Final Research White Paper and Funding Request

Dear Bob, Paul, and Mikael,



I hope this note finds you well. I wanted to follow-up on the email that I originally sent to you below on March 1, 2017, as we have not yet heard from your team. Please let us know if you have any questions or require any additional information to assist in your deliberations about the PACT initiative.

If a quick discussion would aid your consideration of this effort, we would be happy to arrange a teleconference. Please just provide us with the names of the individuals we should work with to organize. If you would rather meet in person and will be attending AACR, Stacey Adam and I are available to meet in DC during the meeting between April 2<sup>nd</sup> at 4pm and April 4<sup>th</sup> in the early afternoon. We have a few meetings scheduled with other members of PACT already, but can be flexible.

I have attached the PACT whitepaper, executive summary, and briefing slides again for your easy access and reference.

Thank you again for the time and effort you have contributed to PACT thus far. We look forward to hearing from you.

Best,  
David Wholley

---

**From:** Melencio, Cheryl (FNIH) [T] **On Behalf Of** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, March 01, 2017 9:19 AM  
**To:** 'robert.abraham@pfizer.com' <robert.abraham@pfizer.com>; 'paul.rejto@pfizer.com' <paul.rejto@pfizer.com>; Dolsten, Mikael <mikael.dolsten@pfizer.com>  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; Donnelly, Meredith (FNIH) [T] <mddonnelly@fnihi.org>; Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** Partnership for Accelerating Cancer Therapies (PACT) - Final Research White Paper and Funding Request

Dear Bob, Paul, and Mikael,

I am reaching out on behalf of FNIH and the PACT Design Team to thank you for your participation in the Design Phase for the Partnership for Accelerating Cancer Therapies. We are pleased to be able to now provide you with the final design whitepaper that your company members and the rest of the PACT Design Team have so worked so hard to create.

You will recall that this white paper was assembled following discussions that your company that began last summer about a new Cancer Moonshot-related public-private partnership (PPP) that the NIH/NCI was interested in forming to address some of the challenges facing the development of immunotherapies and related combination therapies in oncology.

We hope you will feel as our PACT team did that the initial research plan laid out in the white paper addresses these challenges both effectively and efficiently, making the most of investments and expertise available from both public and private sector partners. We are now asking that private sector partners consider investing alongside NIH to provide the matching financial funds needed over the next

five years to support PACT. In addition to the white paper, we have included a set of PowerPoint slides and a short executive summary to help in your internal decision-making process.

We would like to set up a call at your earliest convenience to discuss this project and our request for your company's continued support. Please let myself ([dwholley@fnihi.org](mailto:dwholley@fnihi.org)) and Stacey Adam ([sadam@fnihi.org](mailto:sadam@fnihi.org)) know whom we should work with to arrange this discussion.

Once again, thank you for all the hard work that your company member dedicated to this effort already. It has been a pleasure working with Bob and Paul. And thank you for your consideration of our request for your continued financial participation in the project.

Sincerely,  
David Wholley

**Director of Research Partnerships**

Foundation for the National Institutes of Health  
9650 Rockville Pike | Bethesda, MD 20814 | [www.fnihi.org](http://www.fnihi.org)  
<image001.png>

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards*.

**Cheryl Melencio**

Executive Assistant, Research Partnerships  
Foundation for the National Institutes of Health  
9650 Rockville Pike | Bethesda, MD 20814 | [www.fnihi.org](http://www.fnihi.org)  
Direct (b) (6) | Fax (301) 480-2752

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Combined Federal Campaign (CFC) #29165

For 13 consecutive years, Charity Navigator has rated the FNIH as an organization that *exceeds industry standards*.

<image002.jpg>

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 11 Apr 2017 21:55:35 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: For Hever members: AMP Parkinson's Disease update

Thanks!

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, April 11, 2017 9:46 PM  
**To:** Jill Payne <jill@ptbusinessgroups.com>  
**Cc:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>  
**Subject:** For Hever members: AMP Parkinson's Disease update

Hi Jill,

Here's the second message, this one to see if there are other HEVER members interested in the new Parkinson's disease plan as part of the Accelerating Medicines Partnership (AMP). Please forward to members.

Many thanks, Francis

---

Dear HEVER members:

It was a pleasure meeting with you all this past weekend. As I noted in my talk on Saturday, we are very pleased to be readying the launch of a new AMP initiative focused on Parkinson's disease (AMP-PD). The current projected budget for AMP-PD over five years currently totals (b) (4) to be contributed by NIH, and commitments (b) (4) (through the Foundation for the NIH, FNIH) from each of five private sector partners: GSK, the Michael J. Fox Foundation, Pfizer, Sanofi, and Verily. As I mentioned, by agreement among the partners AMP-PD will initially focus on developing biomarkers to support better clinical trial designs in PD.

In the event that some of your companies may be interested in joining the current partners in AMP-PD, I've attached an executive summary of where the partnership stands, along with a slide deck and the original "white paper" research proposal for those who may want more detail. FNIH is planning a face to face meeting of all the partners on June 1-2 in the DC area to refine the white paper into a detailed research plan with final budgets, timelines, logistics and milestones. There is still some time to consider joining AMP-PD, therefore -- but FNIH has asked that if you have any interest in doing so that you at least signal that to David Wholley or Rosa Canet-Aviles (copied) by May 1.

All the best, the NIH Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 11 Oct 2017 19:25:33 +0000  
**To:** Myles, Renate (NIH/OD) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Just got off the phone with Daniel Levine at BMS

Great!

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

---

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Wednesday, October 11, 2017 3:05 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Just got off the phone with Daniel Levine at BMS

I just received the attached email from BMS. They cleared the release with no changes, and said they should have a quote to me in the next 15 minutes. Rep will be:

Chris Pernie,  
Head of Federal Policy and Gov't Affairs

Still waiting on a quote from the Acting Secretary.

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, October 11, 2017 3:00 PM  
**To:** Myles, Renate (NIH/OD) [E] (b) (6)  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Just got off the phone with Daniel Levine at BMS  
**Importance:** High

1. They are working with their public affairs group on a representative for tomorrow's meeting—likely to be someone from their government affairs group in DC, but Daniel will let you know by end of day.
2. Daniel believes you should have received the press release back with approval/changes. Did you?
3. As for getting a quote from BMS—or in the event you are also still looking for feedback on the release—please contact Sara Koenig who is the R&D public affairs officer for BMS at [sarah.koenig@bms.com](mailto:sarah.koenig@bms.com) and copy Daniel.

Please let me know if I may be of further assistance. David

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*



**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 7 Jun 2017 09:52:09 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Materials for AMP EC Pre-Call tomorrow AM

No I understand. And congratulations!!  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Wednesday, June 7, 2017 9:03 AM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** RE: Materials for AMP EC Pre-Call tomorrow AM

I'll get to it today, sorry about delay

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, June 06, 2017 3:05 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** FW: Materials for AMP EC Pre-Call tomorrow AM  
**Importance:** High

Hi Francis: Did you get a chance to look at this over the weekend? Is it OK to send it to the other EC members? I'd like to give them a little extra time to read and digest it before next Monday's EC call.  
Thanks, David

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, May 31, 2017 6:46 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)>  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <[rcanet-aviles@fnih.org](mailto:rcanet-aviles@fnih.org)>; Hoffmann, Steve (FNIH) [T] <[shoffmann@fnih.org](mailto:shoffmann@fnih.org)>; Vardanian, Lilit (FNIH) [T] <[lvardanian@fnih.org](mailto:lvardanian@fnih.org)>; Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>; Wood, Gretchen (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); NIHDirectorMeetings <[NIHDirectorMeetings@mail.nih.gov](mailto:NIHDirectorMeetings@mail.nih.gov)>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Lea, Allison (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** Materials for AMP EC Pre-Call tomorrow AM  
**Importance:** High

Francis:

Here are the materials for tomorrow's (early) morning AMP EC pre-call:

- Draft meeting slides
- Minutes from Feb. 27 meeting
- Latest attendee roster (attendance overall looks promising)

(b) (5)

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 9 Jun 2017 09:13:38 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Canet-Aviles, Rosa (FNIH) [T]; Hoffmann, Steve (FNIH) [T]; Vardanian, Lilit (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wood, Gretchen (NIH/OD) [E]; Di Mantova, Emma (NIH/OD) [E]; Boskent, Celeste (NIH/OD) [E]; NIHDirectorMeetings; Gadbois, Ellen (NIH/OD) [E]; Lea, Allison (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** RE: Materials for AMP EC Pre-Call tomorrow AM

Thanks for the input Francis. I am out in San Diego for the AMP T2D meeting and was about to send out the slides. I have gone through and increased the font size where I could, but many slides remain too wordy. This is our responsibility and we will address it. I do have to say that we have tried to work with the co-chairs on this— (b) (5)

(b) (5)

(b) (5) I think that will help. I am seeing Phil and Melissa this morning. Meanwhile hopefully the slides I am sending out now will be at least slightly better. David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 09, 2017 5:41 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>; Hoffmann, Steve (FNIH) [T] <shoffmann@fnihi.org>; Vardanian, Lilit (FNIH) [T] <lvardanian@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>; Wood, Gretchen (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Lea, Allison (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** RE: Materials for AMP EC Pre-Call tomorrow AM

Hi David,

I apologize for being so tardy in looking over the materials for the AMP EC. It's been quite a week. I

(b) (5)

(b) (5) But I know time is running out. So please go ahead and send out some version of the file today.

Francis

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, May 31, 2017 6:46 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Canet-Aviles, Rosa (FNIH) [T] <rcanet-aviles@fnihi.org>; Hoffmann, Steve (FNIH) [T]



<shoffmann@fnihi.org>; Vardanian, Lilit (FNIH) [T] <lvardanian@fnihi.org>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnihi.org>; Wood, Gretchen (NIH/OD) [E] (b) (6); Di Mantova, Emma (NIH/OD) [E] (b) (6); Boskent, Celeste (NIH/OD) [E] (b) (6); NIHDirectorMeetings <NIHDirectorMeetings@mail.nih.gov>; Gadbois, Ellen (NIH/OD) [E] (b) (6); Lea, Allison (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)

**Subject:** Materials for AMP EC Pre-Call tomorrow AM

**Importance:** High

Francis:

Here are the materials for tomorrow's (early) morning AMP EC pre-call:

- Draft meeting slides
- Minutes from Feb. 27 meeting
- Latest attendee roster (attendance overall looks promising)

(b) (5)

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 2 May 2017 17:36:10 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]  
**Subject:** RE: Maybe Celgene could be interested in PACT after all?

Absolutely. Will get you something appropriate in the AM.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, May 02, 2017 4:35 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshow, James (NIH/NCI) [E]  
(b) (6)  
**Subject:** Maybe Celgene could be interested in PACT after all?

Hi David,

At the Milken LA meeting I had an interesting conversation with Mark Alles, who is the CEO of Celgene. He spoke on a panel about cancer immunotherapy and highlighted the critical importance of better biomarkers for immunotherapy. So I talked to him afterward to see if he was aware of PACT's goals in exactly this space, and he was not. He wanted me to send him more information and suggested that Celgene might very well want to take part.

(b) (4)

Can you draft a note that I could send to Mark, including the white paper as an attachment?

Tx, FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 19 Oct 2017 02:53:45 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Cc:** Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** Re: New PPPs for pain meds and OUD treatment

Yes, and is he ok with inviting them to call on Friday (he should be--lets just make sure no issues)

Sent from my BlackBerry 10 smartphone.

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Wednesday, October 18, 2017 10:32 PM  
**To:** Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Cc:** Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** RE: New PPPs for pain meds and OUD treatment

Happy to inform Bill – the news is that Ellen, Celia and Allison will serve as FDA liaisons?

Thanks,  
Rebecca

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, October 18, 2017 5:24 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]  
(b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Cc:** Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** FW: New PPPs for pain meds and OUD treatment

All: As promised from my conversation on Monday with Janet Woodcock. Should these folks be invited to Friday's call? If so, should Rebecca be the one to let Bill Chin know? Thanks, David

David Wholley  
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---

**From:** Hertz, Sharon H (b) (6)  
**Sent:** Wednesday, October 18, 2017 4:59 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fni.h.org>  
**Cc:** Winchell, Celia J (FDA/CDER) (b) (6); Fields, Ellen (FDA/CDER) (b) (6)  
**Subject:** New PPPs for pain meds and OUD treatment

Hi,

After discussing this with Dr. Woodcock, I am reaching out to let you know that Ellen Fields will be participating as the primary representative for the new pain meds PPP and Celia Winchell for the OUD treatment PPP. Allison Lin will also be participating from our division.

Thank you,  
Sharon

Sharon Hertz, MD  
Division Director  
Division of Anesthesia, Analgesia, and Addiction Products  
FDA/CDER  
HFD-170, WO 22, Rm (b) (6)  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

(b) (6)  
301 796-7413 Fax

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 10 Oct 2017 21:02:50 +0000  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Pritchett, Anne; Koch, Kellie  
**Subject:** RE: Next Steps

Hi Bill, glad to talk. How best to reach you?

David Wholley  
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**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, October 10, 2017 3:11 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Pritchett, Anne <APritchett@phrma.org>; Koch, Kellie <KKoch@phrma.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** RE: Next Steps

Francis, This makes perfect sense especially thinking about an announcement sooner rather than later. I'll call David to ask how we can help, for instance, to assure timely responses, etc from representatives of our member companies while we really have their attention. Also, I can update him on the PhRMA contribution to the planning effort [we just need Maria's signature and we'll turn around the payment immediately] with a focus on additional \$\$\$ ☺ Bill

---

**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Tuesday, October 10, 2017 12:24 PM  
**To:** Chin, Bill  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Pritchett, Anne  
**Subject:** RE: Next Steps

Hi Bill,

Sure, I'll suggest to David W. that you speak directly with him.

My own ideas here: Establishing leadership of the workstreams, and doing the due diligence consultations, is the most important first step, and we can get started immediately with those activities. That will show the companies that something is happening. David predicts (and I think he has a lot of experience here) that the F2F meeting won't be terribly successful unless those consultations are done first.

None of this says we can't have a public announcement sooner, if that seems to be merited.



Francis

---

**From:** Chin, Bill [<mailto:Chin@phrma.org>]  
**Sent:** Tuesday, October 10, 2017 10:44 AM  
**To:** Pritchett, Anne <[APritchett@phrma.org](mailto:APritchett@phrma.org)>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Next Steps

Of course, I agree with Anne's comments, especially regarding the important need to balance the work flow with the urgency. That said, I truly believe that 6 weeks is too long with due respect to David W. As I have stepped down from my position at PhRMA today, may I'd like to offer any help to expedite the matter. In any case, putting a stake in the ground about the date of the first F2F is important. May I suggest that I speak to David W directly to chat about options? In the meantime, I will be sending the signed agreement for the planning phase today. Bill

---

**From:** Pritchett, Anne  
**Sent:** Tuesday, October 10, 2017 9:18 AM  
**To:** Baker, Rebecca (NIH/OD) [E]; Chin, Bill  
**Cc:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Next Steps

Francis and Rebecca,

Thank you again for the opportunity to speak on Friday. We appreciate the follow up. 6 weeks sounds very long given you'd previously indicated early Dec. for an action plan. On question I have is whether the WH is going to want to say something on the PPP in conjunction with the release of the Pres. Commission report in Nov.—if you can get better sense re. their expectations that would be helpful. I would think at a minimum we'd collectively want to indicate we have a meeting scheduled but again worried that could be interpreted as lack of urgency. We'd appreciate your thoughts on how to navigate that.

We are receiving a high level of inquiries from companies as we'd collectively communicated sense of urgency around this. The sooner we can outline a timeline of meetings/calls with sense of milestones and deliverables over the next few months that we can communicate to those who have agreed to participate and to our Board that would be very helpful and assist participants in planning. Please let us know whether and how we can assist on that front.

We fully agree regarding the need not to lose momentum, Anne

---

**From:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Sent:** Tuesday, October 10, 2017 7:51 AM  
**To:** Chin, Bill  
**Cc:** Collins, Francis (NIH/OD) [E]; Pritchett, Anne  
**Subject:** Re: Next Steps

Dear Bill,

Thanks again for taking the time to talk with us Friday.

It is important that we keep in communication as this initiative has so many components yet to be defined, and changes so quickly.

We agree on the need to move swiftly on our next action.

We met with our internal team Friday to discuss next steps for planning the partnership. The consensus was some additional work would need to take place before the convening of the first face-to-face meeting. Specifically, we will need to hold preparatory conference calls with participants, and brief NIH and industry co-chairs for each of the partnership work-streams.

On one hand, it would be very ambitious to accomplish all this preparatory work in three weeks. On the other, if we wait too long, we lose momentum and valuable time in this crisis.

On David's advice, we are now thinking about a face-to-face meeting in approximately 6 weeks. Francis has checked with Reed Cordish, and the White House preference would be to plan some sort of announcement that could coincide with that meeting.

Would PhRMA have concerns about this timeline, and if so, what other ways could we satisfy stakeholders while still ensuring the ultimate success of the partnership?

Thanks again for working with us on these issues. We look forward to your thoughts.

Best,

Rebecca

On Oct 9, 2017, at 2:32 PM, Chin, Bill <[Chin@phrma.org](mailto:Chin@phrma.org)> wrote:

Rebecca and Francis, Thanks for our call on Friday. I've had a discussion with Steve and the management committee this morning. We agree with your suggestion to delay any press release in order to synchronize with the WH need to have announcement in the next several weeks. However, we agree that we should plan for the first PPP planning meetings in the next weeks or so. In fact, we ideally would like to let our Board know about such plan this Wednesday as many member companies are asking Anne and me about next steps. Did you learn enough you meeting with David W and the FNIH on Friday afternoon to proceed very soon, or at least to put a stake in the ground and name a date? As we discussed, this could be a back-to-back meetings on PPP#1 and PPP#2 with a short overlap session a la Keystone meetings, etc. I'm available for a chat anytime. Bill

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 16 Oct 2017 13:54:22 +0000  
**To:** Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]  
**Subject:** Re: NINDS action items from friday

I can speak late this afternoon if you wish Walter.  
Sent from my BlackBerry 10 smartphone.

---

**From:** Koroshetz, Walter (NIH/NINDS) [E]  
**Sent:** Monday, October 16, 2017 9:32 AM  
**To:** Wholley, David (FNIH) [T]; Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]  
**Subject:** RE: NINDS action items from friday

Might discuss. [REDACTED] (b) (5)  
w

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Sunday, October 15, 2017 9:12 PM  
**To:** Porter, Linda (NIH/NINDS) [E] [REDACTED] (b) (6); Baker, Rebecca (NIH/OD) [E]  
[REDACTED] (b) (6); Tabak, Lawrence (NIH/OD) [E] [REDACTED] (b) (6); Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6); Wolinetz, Carrie (NIH/OD) [E] [REDACTED] (b) (6); Volkow, Nora (NIH/NIDA) [E] [REDACTED] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
[REDACTED] (b) (6); Stein, Jack (NIH/NIDA) [E] [REDACTED] (b) (6)  
**Cc:** Burklow, John (NIH/OD) [E] [REDACTED] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** RE: NINDS action items from friday

Hi, Linda, thanks for sending this. [REDACTED] (b) (5)  
[REDACTED] (b) (5)  
[REDACTED] (b) (5) thanks

David Wholley  
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**From:** Porter, Linda (NIH/NINDS) [E]  
**Sent:** Sunday, October 15, 2017 6:08 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E]  
[REDACTED] (b) (6); Tabak, Lawrence (NIH/OD) [E] [REDACTED] (b) (6); Collins, Francis (NIH/OD) [E] [REDACTED] (b) (6); Wolinetz, Carrie (NIH/OD) [E] [REDACTED] (b) (6); Volkow,



Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)  
**Cc:** Burklow, John (NIH/OD) [E] (b) (6) Biarnes, Michael (FNIH) [T]  
<[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>  
**Subject:** NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)



Linda

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 16 Oct 2017 01:11:50 +0000  
**To:** Porter, Linda (NIH/NINDS) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]  
**Cc:** Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: NINDS action items from friday

Hi, Linda, thanks for sending this.

(b) (5)

(b) (5)

(b) (5) thanks

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**From:** Porter, Linda (NIH/NINDS) [E]  
**Sent:** Sunday, October 15, 2017 6:08 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)  
**Cc:** Burklow, John (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** NINDS action items from friday

Walter and I made contact and here is the list of recommendations

(b) (5)

Linda

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 14 Nov 2017 00:37:43 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]  
**Subject:** RE: TIME SENSITIVE REQUEST FROM ACTING SECRETARY

(b) (4), (b) (5)

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, November 13, 2017 7:22 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** TIME SENSITIVE REQUEST FROM ACTING SECRETARY

Hi all,

In my regular 1:1 with Acting Secretary Hargan at the end of today, we discussed the research needs/opportunities in opioids. We had sent the same document to him as a pre-read that was shared with the Hill last week (attached), which lists a (b) (4), (b) (5), if we are really pulling out all the stops. I told him about our deep concerns about where this would be coming from, given that the Administration had not promised anything at the time of the President's opioid speech. I told him that I thought companies might be willing to contribute something in the range of

(b) (4), (b) (5)

He wanted to know what NIH could come up with by prioritizing.

(b) (4), (b) (5)


(b) (4), (b) (5)

I told him that we had been getting calls from the Congress, and that there was a reasonable possibility they might provide some funding – referencing the Shaheen et al. letter which asked the POTUS to tell them where the needs were.

It turns out that he is meeting with OMB tomorrow afternoon, and is prepared to make a pitch to them that the Administration ought to act. What he wants from us by midday tomorrow (sooner is better), with cc's to Mary-Sumpter Lapinski, Charles Keckler (who sat in on the meeting), and Jen Moughalian (whom he forgot, and had to be reminded by MSL – interesting) – was a range of what we think might be possible for next year. He didn't specifically ask about the outyears, and I'm much less sanguine about those.

I would think the formula might look something like this:

(b) (4), (b) (5)



(b) (4), (b) (5) Please respond (if possible) this evening. I may need Rebecca's help in turning this into a response to Hargan.

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 14 Nov 2017 02:18:00 +0000  
**To:** Tabak, Lawrence (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]  
**Subject:** RE: TIME SENSITIVE REQUEST FROM ACTING SECRETARY

I agree with Larry.

---

**From:** Tabak, Lawrence (NIH/OD) [E]  
**Sent:** Monday, November 13, 2017 9:17 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** Re: TIME SENSITIVE REQUEST FROM ACTING SECRETARY

Francis,

(b) (4), (b) (5)

Larry

--

---

**From:** Francis Collins (b) (6)  
**Date:** Monday, November 13, 2017 at 7:22 PM  
**To:** "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Volkow, Nora (NIH/NIDA) [E]" (b) (6), "Koroshetz, Walter (NIH/NINDS) [E]" (b) (6), "Stein, Jack (NIH/NIDA) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnih.org>  
**Subject:** TIME SENSITIVE REQUEST FROM ACTING SECRETARY

Hi all,

In my regular 1:1 with Acting Secretary Hargan at the end of today, we discussed the research needs/opportunities in opioids. We had sent the same document to him as a pre-read that was shared with the Hill last week (attached), which lists a (b) (4), (b) (5), if we are really pulling out all the stops. I told him about our deep concerns about where this would be coming from, given that the Administration had not promised anything at the time of the President's opioid speech. I told him that I thought companies might be willing to contribute something in the range of

(b) (4), (b) (5)

He wanted to know what NIH could come up with by prioritizing.

(b) (4), (b) (5)

(b) (4), (b) (5)

I told him that we had been getting calls from the Congress, and that there was a reasonable possibility they might provide some funding – referencing the Shaheen et al. letter which asked the POTUS to tell them where the needs were.

It turns out that he is meeting with OMB tomorrow afternoon, and is prepared to make a pitch to them that the Administration ought to act. What he wants from us by midday tomorrow (sooner is better), with cc's to Mary-Sumpter Lapinski, Charles Keckler (who sat in on the meeting), and Jen Moughalian (whom he forgot, and had to be reminded by MSL – interesting) – was a range of what we think might be possible for next year. He didn't specifically ask about the outyears, and I'm much less sanguine about those.

I would think the formula might look something like this:

(b) (4), (b) (5)

(b) (4), (b) (5)

Please respond (if possible) this evening. I may need Rebecca's help in turning this into a response to Hargan.

FC



**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Feb 2017 08:42:49 -0500  
**To:** Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: TIME SENSITIVE REVIEW: PACT summary and slides

These look great to me, Larry. Thanks for sending.

Sent from my BlackBerry 10 smartphone.

---

**From:** Tabak, Lawrence (NIH/OD) [E]  
**Sent:** Tuesday, February 7, 2017 8:18 AM  
**To:** Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: TIME SENSITIVE REVIEW: PACT summary and slides

Please see my comments and suggested edits in attached.

larry

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Tuesday, February 07, 2017 8:04 AM  
**To:** Tabak, Lawrence (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]  
**Cc:** Collins, Francis (NIH/OD) [E]  
**Subject:** TIME SENSITIVE REVIEW: PACT summary and slides

Good morning,

Please find attached a summary and slides on PACT for a possible presentation to the Department this week. Our colleagues in the Department requested these materials for today, and they have been already reviewed by Dr. Collins.

Could you please let me know of any errors or important omissions by **11 am today?**

Thank you in advance for this quick-turnaround review,

Rebecca

Rebecca Baker, Ph.D.  
Science Policy Analyst  
Office of the Director  
National Institutes of Health  
Bethesda, MD 20892  
Phone: (b) (6)



(b) (6)

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, February 6, 2017 9:52 AM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E]  
(b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T]  
<sadam@fnih.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6) Doroshov, James (NIH/NCI) [E]  
(b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); McManus,  
Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6);  
Allen-Gifford, Patrice (NIH/OD) [E] (b) (6)  
**Subject:** URGENT: \*Response\* PACT summary  
**Importance:** High

Hi Rebecca,

See below – can you prepare some additional information about PACT for a possible HHS Friday morning (Feb. 10) briefing (maybe including Price, if he is confirmed by then)? I would think both text (for which you already have a version, but perhaps it could be expanded a bit) and a brief ppt deck would be useful. I'm looping in David and Stacey, who may have ideas about what to include at this point.

I'm also looping in Doug, Jim, and Anne -- for the actual briefing, Doug should ideally be present along with me and LAT. If Doug is not available, it would be great to have Jim attend.

Note the dramatically short timeline for materials – could you and the team have something drafted by COB today that I could review?

Tx, FC

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**From:** Tabak, Lawrence (NIH/OD) [E]  
**Sent:** Monday, February 06, 2017 9:39 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Schwetz, Tara (NIH/OD) [E] (b) (6)  
**Subject:** FW: \*Response\* PACT summary  
**Importance:** High

Francis,  
It appears the Beachhead team is interested in learning more about PACT. Is Rebecca the best person to draft additional materials? Is there someone to engage at NCI? Let me know what we can do to help.

For the proposed extended briefing, apart from yourself, me (?), who else do you want in the room – Doug?

Thanks,  
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**Sent:** Monday, February 06, 2017 9:33 AM  
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Good morning Larry and Tara,

The beachhead team is requesting PACT background. From the email below for convenience: "any information or materials prepared for internal approval to move forward with the partnership and any work plans?" To whom should we assign the PACT background request---NCI generally or someone in particular?

Also, in Maggie's email, it appears they would like a briefing for a larger beachhead audience and/or the Secretary if he is confirmed this week. Would that be just FC and LAT, with or without the Secretary?

Thank you,  
Patrice

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**Sent:** Monday, February 06, 2017 9:04 AM  
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**Cc:** Koeneman, Sandy (NIH/OD) [E] (b) (6)  
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Patrice:

Good morning, below is a follow up request from the Beachhead Team. Can you please send the information by noon tomorrow?

Also, I asked for a time that works the morning of February 10. Maggie said she'd get back to me so if NIH can just remain vigilant about a potential meeting, I'd appreciate it.

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**Sent:** Sunday, February 05, 2017 1:24 PM  
**To:** Robinson, Wilma (HHS/IOS); Hawkins, Jamar (HHS/OS)  
**Cc:** Stannard, Paula (HHS/IOS); Leggitt, Lance (HHS/IOS)  
**Subject:** RE: PACT summary

Dear Wilma and Jamar,

As noted in the background document NIH provided, this is a significant initiative with a launch that might merit a White House event. As such, we think it's quite possible that the incoming Secretary would want to be involved.

Could NIH provide the beachhead team early this week additional background, such as any information or materials prepared for internal approval to move forward with the partnership and any work plans? Also, we'd appreciate Exec Sec's assistance in working with NIH to coordinate a briefing for the

Secretary soon after his confirmation or, if it appears his confirmation might be delayed, for a broader group of beachhead members this week, including Lance and Paula?

Thank you,  
Maggie

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**From:** Allen-Gifford, Patrice (NIH/OD) [E]  
**Sent:** Monday, January 30, 2017 5:55 PM  
**To:** Robinson, Wilma (HHS/IOS); Wynne, Maggie (HHS/IOS)  
**Cc:** Hawkins, Jamar (HHS/OS)  
**Subject:** PACT summary

Hi Wilma and Maggie –

Drs. Collins and Tabak asked that we forward the attached background regarding the Partnership for Accelerating Cancer Therapies in response to questions at last Friday's meeting with the Beachhead team. Please let us know if you have any questions.

Regards,  
Patrice

Patrice Allen-Gifford  
Director  
Executive Secretariat  
National Institutes of Health  
One Center Drive, B1-46  
Bethesda, MD 20892  
Tel: (b) (6)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 2 Oct 2017 18:58:59 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]  
**Subject:** Re: Update on PACT?

(b) (4), (b) (5)

Thanks

Sent from my BlackBerry 10 smartphone.

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**To:** Wholley, David (FNIH) [T]  
**Cc:** Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]  
**Subject:** RE: Update on PACT?

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**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Myles, Renate (NIH/OD) [E] (b) (6)  
**Subject:** FW: Update on PACT?

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Thanks, David

David Wholley  
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**From:** (b) (4)  
**Sent:** Monday, October 02, 2017 12:34 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Subject:** RE: Update on PACT?

David,

(b) (4)

Best regards,

(b) (4)

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**From:** Wholley, David (FNIH) [T] [<mailto:dwholley@fnih.org>]  
**Sent:** Monday, October 02, 2017 9:45 AM  
**To:** (b) (4)  
**Cc:** Adam, Stacey (FNIH) [T]  
**Subject:** RE: Update on PACT?

(b) (4)

NIH is moving forward with their communications and announcement plan for the 12<sup>th</sup>, and are asking me for status.  
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**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Cc:** (b) (4) Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>  
**Subject:** RE: Update on PACT?

David,

I apologize for the delays

(b) (4)

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**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]

**Sent:** Tuesday, September 26, 2017 4:20 PM

**To:** (b) (4), (b) (6)

**Cc:** Adam, Stacey (FNIH) [T]

**Subject:** RE: Update on PACT?

(b) (4), (b) (6)

The announcement of the launch of the Partnership to Advance Cancer Therapies (PACT) is almost certainly going to be on October 12, at the National Press Club. (b) (4)

Thanks, David

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**From:** (b) (4), (b) (6)

**Sent:** Monday, September 18, 2017 5:49 PM

**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>

**Cc:** (b) (4) Adam, Stacey (FNIH) [T] <sadam@fnih.org>

**Subject:** Re: Update on PACT?

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Sorry for the delayed reply. (b) (6)

We are still in the process (b) (4) I will see if I can get a more definitive answer this week.

Best regards,  
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Sent from my iPhone

On Sep 15, 2017, at 2:47 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

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(b) (4) we are trying to confirm direction from the last couple of interested companies.

Please let me know, or any additional information I can supply you.

Best regards,

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**Cc:** Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 2 Oct 2017 20:08:16 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Update on PACT?

(b) (4), (b) (5)

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, October 2, 2017 3:00 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Adam, Stacey (FNIH) [T]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]  
**Subject:** RE: Update on PACT?

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FC

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**From:** Wholley, David (FNIH) [T]  
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**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Myles, Renate (NIH/OD) [E] (b) (6)  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 6 Feb 2017 10:13:06 -0500  
**To:** Lowy, Douglas (NIH/NCI) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Tabak, Lawrence (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Doroshow, James (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Allen-Gifford, Patrice (NIH/OD) [E]  
**Subject:** RE: URGENT: \*Response\* PACT summary

We have some materials that may help; are getting on the phone with Rebecca and Allison in 5 minutes to discuss. Sounds exciting.

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Monday, February 06, 2017 9:58 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Doroshow, James (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Allen-Gifford, Patrice (NIH/OD) [E] (b) (6)  
**Subject:** Re: URGENT: \*Response\* PACT summary

Hi Francis: I'm available Friday morning. Doug

---

**From:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Date:** Monday, February 6, 2017 at 9:52 AM  
**To:** "Baker, Rebecca (NIH/OD) [E]" (b) (6)  
**Cc:** "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Schwetz, Tara (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Adam, Stacey (FNIH) [T]" <sadam@fnih.org>, "Lowy, Douglas" (b) (6), "Doroshow, James (NIH/NCI) [E]" (b) (6), "Lubenow, Anne (NIH/NCI) [E]" (b) (6), "McManus, Ayanna (NIH/OD) [E]" (b) (6), "Wood, Gretchen (NIH/OD) [E]" (b) (6), "Allen-Gifford, Patrice (NIH/OD) [E]" (b) (6)  
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**Importance:** High

Francis,

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Thanks,  
larry

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Patrice

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**Cc:** Koeneman, Sandy (NIH/OD) [E] (b) (6)  
**Subject:** \*Response\* PACT summary



Patrice:

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Also, I asked for a time that works the morning of February 10. Maggie said she'd get back to me so if NIH can just remain vigilant about a potential meeting, I'd appreciate it.

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**Subject:** RE: PACT summary

Dear Wilma and Jamar,

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Thank you,  
Maggie

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**From:** Allen-Gifford, Patrice (NIH/OD) [E]  
**Sent:** Monday, January 30, 2017 5:55 PM  
**To:** Robinson, Wilma (HHS/IOS); Wynne, Maggie (HHS/IOS)  
**Cc:** Hawkins, Jamar (HHS/OS)  
**Subject:** PACT summary

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Regards,  
Patrice

Patrice Allen-Gifford  
Director  
Executive Secretariat

National Institutes of Health  
One Center Drive, B1-46  
Bethesda, MD 20892  
Tel: [REDACTED] (b) (6)



**From:** Wholley, David (FNIH) [T]  
**Sent:** Sat, 21 Oct 2017 01:25:10 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Burklow, John (NIH/OD) [E]  
**Subject:** RE: URGENT: need feedback tonight on next steps for opioid PPP

(b) (5)

(b) (5) Francis.

David Wholley  
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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, October 20, 2017 6:06 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T]  
<dwholley@fnih.org>  
**Subject:** URGENT: need feedback tonight on next steps for opioid PPP

Hi all,

Many thanks to Rebecca for putting together this draft of the solicitation we need to send out ASAP to the participating companies, following today's conference call.

I think this looks like a good list. Nora and Walter, are you OK with this? I'm also looping in David Wholley to seek his advice. Perhaps this time we should ask for two kinds of rating (b) (4), (b) (5)  
(b) (4), (b) (5)

Though it would be great to know, (b) (4), (b) (5)  
(b) (4), (b) (5)

FC

---

**From:** Baker, Rebecca (NIH/OD) [E]

**Sent:** Friday, October 20, 2017 3:39 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E]

(b) (6); Burklow, John (NIH/OD) [E] (b) (6)

**Subject:** Follow up: Invitation for first meeting of PPP to address the opioid crisis - Friday October 20, 11AM EDT

Good afternoon,

In follow up to today's discussion with industry partners, I am drafting a follow up note to capture interest in the possible PPP areas.

For your notes, please find below a new/revised list of possible areas of interest to ask of companies in response to today's discussion.

A similar set of requests was sent out in September in advance of the PhRMA BMAC meeting (September results attached), which we can refer to gently in our note.

New ideas coming out of today's discussion are marked in green.

With regard to planning for next week, it was my impression that this request would be to participate in the next stage of the planning process. If we are anticipating a White House event next week, this sorting exercise may not give us much new fodder for an announcement.

If we would like to be able to provide more information about what companies are planning to contribute, we might couple the interest poll with a request for information about in kind support.

This could be similar to what Bill shared in his weekend note (attached), which seems to be not limited to PhRMA groups.

In addition to the interest poll, is there any other information we should ask the companies for in the note we send tonight?

Thanks for your thoughts,

Rebecca

(b) (5)

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**From:** Baker, Rebecca (NIH/OD) [E]

**Sent:** Thursday, October 19, 2017 11:58 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6)>

**Cc:** Johnson, Ellie (NIH/NIDA) [E] <[johnsone@mail.nih.gov](mailto:johnsone@mail.nih.gov)>; NIHDirectorMeetings <[NIHDirectorMeetings@mail.nih.gov](mailto:NIHDirectorMeetings@mail.nih.gov)>; Walker, Paula (NIH/NINDS) [E] <(b) (6)>; McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Welch, Will (NIH/CIT) [C] (b) (6)

**Subject:** FW: Meeting Materials: Invitation for first meeting of PPP to address the opioid crisis - Friday October 20, 11AM EDT

NIH team,

Attached are a few additional material's for tomorrow's call:

1. Integrated slide presentation
2. Agenda
3. Roster of participating companies, current as of tonight
4. Original straw poll results of PhRMA companies who participated in September meetings

We have reserved space in Building 31, 6C room 7, adjacent to the CCRHB meetings so folks can step in and out.

Walter and Jack, dial-in information is below.

Thanks and see you tomorrow,

Rebecca

(b) (6)  
Meeting number (access code): (b) (6)  
Meeting password: (b) (6)

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**From:** Baker, Rebecca (NIH/OD) [E]

**Sent:** Thursday, October 19, 2017 6:03 PM

**To:** [Mark.Namchuk@alkermes.com](mailto:Mark.Namchuk@alkermes.com); [Markus.Haeberlein@alkermes.com](mailto:Markus.Haeberlein@alkermes.com); [Armin.szegedi@allergan.com](mailto:Armin.szegedi@allergan.com); [jdunlop@amgen.com](mailto:jdunlop@amgen.com); [gerard.marek@astellas.com](mailto:gerard.marek@astellas.com); [tolga.uz@astellas.com](mailto:tolga.uz@astellas.com); [pam.cyrus@bayer.com](mailto:pam.cyrus@bayer.com); [james.baxter@boehringerelgelheim.com](mailto:james.baxter@boehringerelgelheim.com); [alfred.sandrock@biogen.com](mailto:alfred.sandrock@biogen.com); [Kate.dawson@biogen.com](mailto:Kate.dawson@biogen.com); [rihargreaves@celgene.com](mailto:rihargreaves@celgene.com); [jfreeman@celgene.com](mailto:jfreeman@celgene.com); [ktruit@dsi.com](mailto:ktruit@dsi.com); [andrew\\_satlin@eisai.com](mailto:andrew_satlin@eisai.com); [laszlo.radvanyi@emdserono.com](mailto:laszlo.radvanyi@emdserono.com); [cflores2@its.jnj.com](mailto:cflores2@its.jnj.com); [andyahn@lilly.com](mailto:andyahn@lilly.com); [mintun@avidrp.com](mailto:mintun@avidrp.com); [Min.x.li@gsk.com](mailto:Min.x.li@gsk.com); [Murray.w.steward@gsk.com](mailto:Murray.w.steward@gsk.com); [BKIN@Lundbeck.com](mailto:BKIN@Lundbeck.com); [DTOL@Lundbeck.com](mailto:DTOL@Lundbeck.com); [david.michelson@merck.com](mailto:david.michelson@merck.com); [allen.templeton@merck.com](mailto:allen.templeton@merck.com); [Candace.saldarini@ODHsolutions.com](mailto:Candace.saldarini@ODHsolutions.com); [rmalamut@avanir.com](mailto:rmalamut@avanir.com); [Kenneth.m.verburg@pfizer.com](mailto:Kenneth.m.verburg@pfizer.com); [Don.Kyle@pharma.com](mailto:Don.Kyle@pharma.com); [Rita.BaliceGordon@Sanofi.com](mailto:Rita.BaliceGordon@Sanofi.com); [Kenneth.koblan@sunovion.com](mailto:Kenneth.koblan@sunovion.com); [Gregg.redeker@takeda.com](mailto:Gregg.redeker@takeda.com); [Patricio.ODonnell@takeda.com](mailto:Patricio.ODonnell@takeda.com); [Ernest.kopecky@tevapharm.com](mailto:Ernest.kopecky@tevapharm.com); [Eunan.maguire@adaptpharma.com](mailto:Eunan.maguire@adaptpharma.com); [Fintan.keegan@adaptpharma.com](mailto:Fintan.keegan@adaptpharma.com); [john.dunlop@amgen.com](mailto:john.dunlop@amgen.com); [Rafael.carbunaru@bsci.com](mailto:Rafael.carbunaru@bsci.com); [kbrose@chanzuckerberg.com](mailto:kbrose@chanzuckerberg.com); [bdhammock@ucdavis.edu](mailto:bdhammock@ucdavis.edu); [schmidtwwk@sbcglobal.net](mailto:schmidtwwk@sbcglobal.net); [Christian.Heidbreder@indivior.com](mailto:Christian.Heidbreder@indivior.com); [anne.esposito@Indivior.com](mailto:anne.esposito@Indivior.com); [Szale@lyndra.com](mailto:Szale@lyndra.com); [GFujii@molecularxpress.com](mailto:GFujii@molecularxpress.com); [sdoberstein@nektar.com](mailto:sdoberstein@nektar.com); [pskolnick@opiant.com](mailto:pskolnick@opiant.com); [rmalamut@avanir.com](mailto:rmalamut@avanir.com); [owen.mcmanus@qstatebio.com](mailto:owen.mcmanus@qstatebio.com); [kbeebe@titanpharm.com](mailto:kbeebe@titanpharm.com); [mlark@trevena.com](mailto:mlark@trevena.com); [acrombie@trevena.com](mailto:acrombie@trevena.com)

**Cc:** [Chin@phrma.org](mailto:Chin@phrma.org); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); Johnson, Ellie (NIH/NIDA) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); NIHDirectorMeetings <[NIHDirectorMeetings@mail.nih.gov](mailto:NIHDirectorMeetings@mail.nih.gov)>; Fields, Ellen (FDA/CDER) (b) (6); Winchell, Celia J (FDA/CDER) (b) (6); Lin, Allison (FDA/CDER) (b) (6)

**Subject:** Meeting Materials: Invitation for first meeting of PPP to address the opioid crisis - Friday October 20, 11AM EDT

Good afternoon,

Please find attached materials for tomorrow's teleconference.

WebEx information can be found in the agenda, and is also pasted below.

Please feel free to reach out with any questions.



Thank you,

Rebecca

### Join WebEx meeting

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

### Join by phone

(b) (6) Call-in toll number (US/Canada)

Global call-in numbers

Can't join the meeting?

---

**From:** Collins, Francis (NIH/OD) [E]

**Sent:** Tuesday, October 17, 2017 6:50 PM

**To:** Eunan.maguire@adaptpharma.com; Fintan.keegan@adaptpharma.com; Mark.Namchuk@alkermes.com; Markus.Haeberlein <Markus.Haeberlein@alkermes.com>; Armin.Szegedi@allergan.com; john.dunlop@amgen.com; pam.cyrus@bayer.com; alfred.sandrock@biogen.com; Rafael.carbunaru@bsci.com; rihargreaves@celgene.com; jfreeman@celgene.com; kbrose@chanzuckerberg.com; ktruit@dsi.com; bdhammock@ucdavis.edu; andrew\_satlin@eisai.com; andy.ahn@lilly.com; mintun@avidrp.com; schmidtwk@sbcglobal.net; laszlo.radvanyi@emdserono.com; "Min.x.li@gsk.com; Murray.w.steward@gsk.com; "; Christian.Heidbreder@indivior.com; cflores2@its.jnj.com; Steve Zale <Szale@lyndra.com>; allen.templeton@merck.com; david.michelson@merck.com; GFujii@molecularexpress.com; sdoberstein@nektar.com; pskolnick@opiant.com; "Candace.saldarini@ODHsolutions.com; rmalamut@avanir.com; Don.Kyle@pharma.com; Richard.Mannion@pharma.com; Kenneth.m.verburg@pfizer.com; owen.mcmanus@qstatebio.com; Rita.Balice-Gordon@sanofi.com; Kenneth.koblan@sunovion.com; gregg.redeker@takeda.com; Patricio.ODonnell@takeda.com; Ernest.Kopecky@tevapharm.com; kbeebe@titanpharm.com; "mlark@trevena.com; acrombie@trevena.com

**Cc:** Chin@phrma.org; Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Tabak, Lawrence (NIH/OD) [E] (b) (6)

**Subject:** Invitation for first meeting of PPP to address the opioid crisis - Friday October 20, 11AM

Dear Colleague,

Thank you for agreeing to participate in the development of a public-private partnership to address the national opioid crisis. As you know, our discussions to date have allowed us to focus on two areas for the partnership:

1. Develop new formulations and combinations of medications to treat opioid use disorders and prevent and reverse overdose
2. Develop new non-addictive pain therapies.

The next steps involve putting these focus areas into action which will entail convening experts from industry, academia, and the Foundation for the NIH. We will be asking you to commit to participating in a series of teleconferences (a couple of hours each) over the next several weeks and at least one in-person full-day meeting in November or December to establish consensus on a high-level plan. Given the magnitude of the crisis, and the strong interest of the current Administration and the Congress in finding solutions, we'd like to solidify a plan and identify any initial funding commitments by the end of this year, with a view to beginning work in early 2018.

In order to launch the planning effort, we are inviting you to participate in an inaugural conference call this **Friday, October 20, from 11:00 AM to 12:30 PM** Eastern U.S. time. We will outline our current thinking on potential research projects, describe the planning process we propose to follow, identify industry, NIH/academic chairpersons for these efforts, and seek your feedback.

Please find below the call-in and WebEx information; please RSVP to Rebecca Baker at

(b) (6)

We look forward to your joining us this Friday and to working with you on addressing this major public health challenge.

Regards,

Francis S. Collins, M.D., Ph.D.  
Director, NIH

Stephen J. Ubl  
President and Chief Executive Office, PhRMA

#### Join WebEx meeting

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

#### Join by phone

(b) (6) Call-in toll number (US/Canada)

Global call-in numbers

Can't join the meeting?

If you are a host, [go here](#) to view host information.

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 16 Jun 2017 14:35:36 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: What needs to be done?

(b) (5)

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Friday, June 16, 2017 2:28 PM  
**To:** Wholley, David (FNIH) [T]  
**Subject:** Fwd: What needs to be done?

Sent from my iPhone

Begin forwarded message:

**From:** "Austin, Christopher (NIH/NCATS) [E]" (b) (6)  
**Date:** June 16, 2017 at 2:18:38 PM EDT  
**To:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Subject:** Re: What needs to be done?

(b) (5)



(b) (5)

Chris

Sent from my iPhone

On Jun 16, 2017, at 2:03 PM, Collins, Francis (NIH/OD) [E] (b) (6) wrote:  
I had to step out for a while. Now the meeting seems a bit sleepy. What are the top 3-4 things that are needed and that could be accomplished by a partnership ?  
Sent from my iPhone

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 16 Jun 2017 14:25:59 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Where this is going

There is nothing below?

Sent from my BlackBerry 10 smartphone.

Original Message

From: Collins, Francis (NIH/OD) [E]

Sent: Friday, June 16, 2017 2:20 PM

To: Wholley, David (FNIH) [T]

Subject: Where this is going

See below. Agree? Add? subtract?

Sent from my iPhone

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 9 Nov 2017 00:29:01 +0000  
**To:** Chin, Bill  
**Cc:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Re: Who Would Develop A Discarded Asset?

I think next step would be to [REDACTED]

(b) (4)

(b) (4)

Sent from my BlackBerry 10 smartphone.

---

**From:** Chin, Bill  
**Sent:** Wednesday, November 8, 2017 7:21 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Who Would Develop A Discarded Asset?

David, I just spoke to my former Lilly colleague, Rob Armstrong, who is currently CEO, Boston Pharmaceuticals [<http://www.bostonpharmaceuticals.com/whatwedo.php>]. His company essentially takes discarded assets, or repurposes same, and seeks to develop them. I asked him what models might be employed to perform this translational work. He suggested 3 approaches. [REDACTED]

(b) (4)

(b) (4)

[REDACTED]

(b) (4) Rob would entertain a call, if you wish. His email = [rob@bostonpharmaceutical.com](mailto:rob@bostonpharmaceutical.com) Let me know if I can answer any questions. Bill

PS Francis— [REDACTED]

(b) (4)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Fri, 10 Mar 2017 14:22:26 -0500  
**To:** Lundberg, Jan  
**Cc:** Edith Van Putten (vanputte@ohsu.edu)  
**Subject:** Replacement for Francis Cuss

Dear Jan:

As I'm sure you've heard, Francis Cuss has stepped down as CSO of BMS. In discussing this with Francis Collins, we agree that we will need to elect a senior industry R&D executive to replace him on the AMP Executive Committee from among the companies not currently represented (AbbVie, Biogen, BMS, GSK, Janssen, Merck, Sanofi, Takeda), but also to have someone in mind that we think would be best suited to the role and be willing to give some time to it--although we've done a good job of trimming back our required meeting schedule I think. Do you have any thoughts about whom we should think about approaching? HEVER is coming up and it would be good to have some idea(s) before then.

Please let me know. Happy to discuss by phone as well, involve others, etc. as you wish.

Regards,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 3 Oct 2017 18:55:48 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Doroshow, James (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Myles, Renate (NIH/OD) [E]  
**Subject:** (b) (4) - update

Hi all: FYI Stacey Adam and I just got off a longish call with some of the decision-makers on PACT at (b) (4), (b) (5) to answer their questions about the revised design for PACT. It went well and we think (b) (4), (b) (5)  
(b) (4), (b) (5)

David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 02:51:31 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** Template for Opioids Partnership White Paper  
**Attachments:** Opioids Partnership - White Paper Outline 30Nov2017.docx

Francis, all –

Our team put together the attached outline for the White Paper we are producing for Focus Area B (pain). I shared it with Bill Chin and he likes it, but had a couple of requests:

(b) (4), (b) (5)

(b) (4), (b) (5)

Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 22 Nov 2017 21:18:33 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]  
**Subject:** Updated Meeting Schedule  
**Attachments:** Opioid meeting schedule 11-22-17.xlsx

All: for Friday's call. Please copy anyone I may have forgotten.  
Happy Thanksgiving to all.  
David

	OPIOID PARTNERSHIP MEETING SCHEDULES AS OF 11- 22-17						
<b>Project</b>	<b>Co-Chairs</b>	<b>CoChair</b>	<b>Call 1A</b>	<b>Call 1B</b>	<b>Call 2</b>	<b>Call 3</b>	<b>Notes</b>
Clinical Trials	Verburg (Pfizer) and Wright (NINDS)	Done	Done	Done	Dec. 1	N/A	Amir Tamiz (NINDS) added as second
Biomarkers	Mintun (Lilly) and Thomas (NIDA)	Done	Done	Done	Dec. 1	N/A	Yolanda Gallego (NIDCR) added as second
Data Sharing	Dunlop (Amgen) and Oshinsky (NIDA)	Done	Done	Nov. 28	Week of Dec. 4	N/A	
Asset Repurpose (SWAT)	Flores (Janssen) and Austin (NCATS)	N/A	Nov. 22	Nov 28,29	Dec 4,5		Flores, Austin, Verburg, Li (GSK), Dunlop, Christine Colvis (NCATS)
<b>Co-Chair Only Meeting - Dec. 7</b>							
<b>FACE TO FACE: DECEMBER 12 and 13, North Bethesda Marriott</b>							


**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 2 Oct 2017 14:36:23 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]  
**Subject:** Where things stand on PACT

Francis,

Given we are "getting down to the wire" I thought I would give you a quick Monday morning update on where things stand with PACT:

- We are still at eight companies that have committed (AbbVie, BMS, Boehringer-Ingelheim, Celgene, Genentech, GSK, Janssen, Pfizer)

(b) (4), (b) (5)



- FNIH is providing support as needed to Renate on the rollout plan.

Please let me know if there is anything else you need at this point.

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 15 Oct 2017 15:24:06 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]  
**Cc:** Burklow, John (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Notes and Follow up: Friday's 5pm pain and opioids meeting

In action items below, please note that my specific requests was for 4-5 academic representatives. On NIH and industry participants I am not looking for representatives but NIH's recommendations on project leads who can act as co-chairs for the design effort. Thanks, David

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

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**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Sunday, October 15, 2017 10:47 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Burklow, John (NIH/OD) [E] (b) (6)  
**Subject:** Notes and Follow up: Friday's 5pm pain and opioids meeting

Good morning,

Attached please find notes from Friday's meeting to discuss the pain and opioid partnership. Action items are also listed below.

Wishing everyone a great Sunday,

Rebecca

(b) (4)

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**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Friday, October 13, 2017 12:27 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>  
**Cc:** NIHDirectorMeetings <[NIHDirectorMeetings@mail.nih.gov](mailto:NIHDirectorMeetings@mail.nih.gov)>; Wood, Gretchen (NIH/OD) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6); Schulke, Hilda (NIH/NIDA) [E] (b) (6); Johnson, Ellie (NIH/NIDA) [E] (b) (6)  
**Subject:** Materials for today's 5pm pain and opioids meeting

Good afternoon,

Materials for today's 5 pm meeting to discuss the partnership on pain and opioids are attached. We will gather in Building 1/Room 116, and teleconference information is below:

Dial In: (b) (6); PC: (b) (6)

I will bring hard copies of all materials.

Thanks,  
Rebecca

Rebecca Baker, Ph.D.  
Science Policy Analyst  
Office of the Director  
National Institutes of Health  
Bethesda, MD 20892  
Phone: (b) (6)  
(b) (6)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 15:43:24 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Notes and follow up: Last week's opioid meetings  
**Attachments:** Notes\_Opioid and Pain PPP Meeting 11-2-2017dwrev.docx, Notes\_Opioid and Pain PPP Meeting 11-3-2017dwrev.docx, Partnership Precip for PhRMA Board 11-6-2017 v2dwrev.docx

Rebecca, thanks for these notes. The strawman precis looks especially good. Attached are my redlined suggested changes and questions on the documents. As for the action items below, I believe we discussed a range of dates from Dec 11 to the 13<sup>th</sup> for the F2F, with two days being chosen depending on people's schedules—and it turns out that Francis and Walter are most available on Dec 11 and 12, so we are moving ahead with those dates. If that is incorrect please let me know immediately. I think there is also some confusion on what groups I am convening when. In my recollection, for Focus Area 2 (pain) we agreed with the plan to convene the individual working groups in data sharing, biomarkers, and clinical trials—not the “full group of private sector partners” --and share the output of those conversations prior to Dec 4 to help refine the document. There was no plan (and no time) for an additional effort to gather all the partners to discuss all these things before Dec. 4. Bill and I were to work over the weekend to lay out a template of what the 5-6 page “business case” for the pharma leaders would need to include (and yes, we did start on this, ball is currently in Bill's court).

One further question: are the results of the survey to the companies sent out after the Oct 20 call (the ones with the 17 columns and the H-M-L ratings) to be considered confidential? Or can I share these with my group co-chairs and beyond?

Thanks, David

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 1:01 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Stein, Jack (NIH/NIDA) [E] (b) (6)  
**Subject:** Notes and follow up: Last week's opioid meetings

Good evening,

In follow-up to our discussions last week on the PPP to address the opioid crisis, please find attached:

1. Notes from our standing meeting on Thursday 11-2-2017
2. Notes from our special meeting with Bill Chin on Thursday 11-3-2017
3. A draft 5-page summary of the partnership, to be further developed by NIH, PhRMA and industry leads before sharing with members of the PhRMA board on 12-4-2017. The document's substance was gathered from our many workshops this Summer and Fall, and revised by NINDS



and NIDA today. In addition, Bill Chin provided a few more parameters -- Nora, Walter, Linda and Jack, please review again and add provisional implementation plans in the new placeholder sections.

Action items are listed below:

(b) (4)



David and I are working with Bill to keep him in the loop.

Please let me know if you have any questions.

Thanks,  
Rebecca

























**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 4 Dec 2017 21:25:19 +0000  
**To:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Porter, Linda (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]  
**Cc:** Volkow, Nora (NIH/NIDA) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Notes and Follow up: Opioids and Pain Partnership Meeting

Carrie, we are trying for a an early draft of slides—or at least an outline thereof—in time for the co-chairs call on Thursday. I anticipate lots of additional material that needs to be filled in, reviewed by more than a few parties, and revised. I expect a final draft of slides to go out no sooner than the day before the meeting, Monday December 11.

David

---

**From:** Wolinetz, Carrie (NIH/OD) [E]  
**Sent:** Monday, December 4, 2017 4:10 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Cc:** Volkow, Nora (NIH/NIDA) [E] (b) (6)  
**Subject:** Re: Notes and Follow up: Opioids and Pain Partnership Meeting

Hi David,

Thanks for the follow up with the white paper outline.

I believe on the call last week you mentioned that you'd be working up to the wire on materials for next week's face to face, but in thinking about maximizing the time at the meeting - especially now that I'm looking at this ambitious outline - it seems like it would be pretty critical to share as much as possible in advance. What is the timeline that you're planning on getting materials out? Is before the weekend feasible? Cheers, Carrie

Carrie D. Wolinetz, Ph.D.  
Acting Chief of Staff and  
Associate Director for Science Policy  
Office of the Director  
National Institutes of Health

(b) (6)

----- Original message -----

From: "Baker, Rebecca (NIH/OD) [E]" <(b) (6)>  
Date: 12/1/17 10:42 AM (GMT-05:00)

To: "Collins, Francis (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]"  
(b) (6), "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Koroshetz,  
Walter (NIH/NINDS) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]"  
(b) (6), "Stein, Jack (NIH/NIDA) [E]" (b) (6), "Wholley, David (FNIH) [T]"  
(b) (6), "Biarnes, Michael (FNIH) [T]" <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>  
Cc: "Volkow, Nora (NIH/NIDA) [E]" (b) (6)  
Subject: Notes and Follow up: Opioids and Pain Partnership Meeting

Good morning,

Attached please find notes and action items from yesterday's pain and opioid meeting. I've also attached an electronic copy of the first-pass of the integrated agenda for Dec 12-13 distributed at the meeting.

Action items are also listed below.



Please let me know if you have any questions or concerns.

Thanks,  
Rebecca

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**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Wednesday, November 29, 2017 5:17 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]  
(b) (6); Wolinetz, Carrie (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Stein, Jack  
(NIH/NIDA) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Cc:** McManus, Ayanna (NIH/OD) [E] (b) (6); NIHDirectorMeetings  
<[NIHDirectorMeetings@mail.nih.gov](mailto:NIHDirectorMeetings@mail.nih.gov)>  
**Subject:** Materials for tomorrow's Opioids and Pain Partnership Meeting

Good afternoon,

Please find attached materials for tomorrow's opioid and pain partnership discussion. We will gather in 1/116. Attachments are also listed below:

Attachment 1 – Notes from conversations with PhRMA

Attachment 2 -- Draft 5-pager for PhRMA

Attachment 3 – Agenda for Dec 11 NIDA/ECRI meeting

Attachment 4 – Agenda for Dec 12-13 face-to-face partnership meeting

Thanks and see you tomorrow,

Rebecca

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 26 Oct 2017 19:12:26 +0000  
**To:** Hardesty, Rebecca (NIH/OD) [C]; Hallett, Adrienne (NIH/OD) [E]; McGarey, Barbara (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Johnson, Alfred (NIH/OD) [E]; Godin, Jacquelyn (NIH/OD) [E]  
**Cc:** Burrus-Shaw, Cyndi (NIH/OD) [E]; Casselle, Julia (NIH/OD) [C]; Harris, Melissa (NIH/OD) [E]; Schulke, Hilda (NIH/NIDA) [E]; Walker, Paula (NIH/NINDS) [E]  
**Subject:** RE: OMB meeting for Monday!

I will not be able to be on the call (b) (6)

---

**From:** Hardesty, Rebecca (NIH/OD) [C]  
**Sent:** Thursday, October 26, 2017 2:24 PM  
**To:** Hallett, Adrienne (NIH/OD) [E] (b) (6); McGarey, Barbara (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shapiro, Neil (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Godin, Jacquelyn (NIH/OD) [E] (b) (6)  
**Cc:** Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6); Casselle, Julia (NIH/OD) [C] (b) (6); Harris, Melissa (NIH/OD) [E] (b) (6); Schulke, Hilda (NIH/NIDA) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6)  
**Subject:** RE: OMB meeting for Monday!  
**Importance:** High

Hi Everyone,

The meeting is confirmed for 4:30PM today in Building (b) (6) room (b) (6). For those unable to join in person please use the dial-in information below.

Dial-in: (b) (6)  
Participant Code: (b) (6)

Materials will be sent out closer to the start time.

Thank you,

Rebecca

---

**From:** Wolinetz, Carrie (NIH/OD) [E]  
**Sent:** Thursday, October 26, 2017 1:10 PM  
**To:** Hallett, Adrienne (NIH/OD) [E] (b) (6); McGarey, Barbara (NIH/OD) [E]  
(b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD)  
[E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shapiro, Neil  
(NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora  
(NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda  
(NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6)  
Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Hardesty, Rebecca (NIH/OD) [C]  
(b) (6)>; Godin, Jacquelyn (NIH/OD) [E] (b) (6)  
**Subject:** Re: OMB meeting for Monday!

I've asked Rebecca to see if we can pull together a quick meeting/call this afternoon.

Francis, given your commitment this afternoon, we will leave you out of it for now but will return to you shortly with some ideas to noodle upon. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.  
Acting Chief of Staff and  
Associate Director for Science Policy  
Office of the Director  
National Institutes of Health  
(b) (6)

----- Original message -----

**From:** "Hallett, Adrienne (NIH/OD) [E]" (b) (6)  
**Date:** 10/26/17 1:06 PM (GMT-05:00)  
**To:** "McGarey, Barbara (NIH/OD) [E]" (b) (6), "Collins, Francis (NIH/OD)  
[E]" (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6)  
"Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wolinetz, Carrie (NIH/OD) [E]"  
(b) (6), "Shapiro, Neil (NIH/OD) [E]" (b) (6), "Burklow,  
John (NIH/OD) [E]" (b) (6), "Volkow, Nora (NIH/NIDA) [E]"  
(b) (6), "Koroshetz, Walter (NIH/NINDS) [E]"  
(b) (6), "Stein, Jack (NIH/NIDA) [E]" (b) (6), "Porter,  
Linda (NIH/NINDS) [E]" (b) (6), "Johnson, Alfred (NIH/OD) [E]"  
(b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>  
**Subject:** RE: OMB meeting for Monday!

I'm around too.

Just for Barb: (b) (5)  
(b) (5)



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**From:** McGarey, Barbara (NIH/OD) [E]

**Sent:** Thursday, October 26, 2017 1:01 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6) Baker, Rebecca (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shapiro, Neil (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>

**Subject:** RE: OMB meeting for Monday!

Yes – (b) (5)  
(b) (5) I'm around if there is a huddle.

Barb

Barbara M. McGarey, JD

Deputy Associate General Counsel

Office of the General Counsel

Public Health Division, NIH Branch

31 Center Drive, Rm (b) (6)

Bethesda, MD 20892-2111

(b) (6) (p)

(301) 402-1034 (f)

(b) (6)

---

**From:** Collins, Francis (NIH/OD) [E]

**Sent:** Thursday, October 26, 2017 12:28 PM

**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shapiro, Neil

(NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6);

Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]

(b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack

(NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson,

Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>;

McGarey, Barbara (NIH/OD) [E] (b) (6)

**Subject:** OMB meeting for Monday!

Hi All,



Just saw this meeting has been scheduled for 11 am Monday 10/30. We need to provide pre-read by tomorrow. That will need to include a description of the research needs for opioids and pain (pretty much what we've been saying all along, but did we ever get feedback from ASFR?)

And then there needs to be an articulation of how the (b) (5) challenge would work. (b) (5)

(b) (5)

Thoughts? Please share ASAP. Rebecca, can you start a draft?  
FC

Sent from my iPhone

Begin forwarded message:

**From:** "Collins, Francis (NIH/OD) [E]" (b) (6)

**Date:** October 25, 2017 at 7:30:03 PM EDT

**To:** "Grogan, Joseph J. EOP/OMB" (b) (6), "Mulvaney, Mick M. EOP/OMB" (b) (6), "Cordish, Reed S. EOP/WHO"

(b) (6)

**Cc:** "Georges, Liza B. EOP/WHO" (b) (6)

**Subject:** RE:

Of course. On it.

Francis

-----Original Message-----

**From:** Grogan, Joseph J. EOP/OMB (b) (6)

**Sent:** Wednesday, October 25, 2017 5:37 PM

**To:** Mulvaney, Mick M. EOP/OMB (b) (6); Cordish, Reed S. EOP/WHO (b) (6); Collins, Francis (NIH/OD) [E]

(b) (6)

**Cc:** Georges, Liza B. EOP/WHO (b) (6)

**Subject:** RE:

Yes. And Dr. Collins, if you have any paper on it -- even if rough -- that would be helpful to prepare. Thank you, Joe

-----Original Message-----

**From:** Mulvaney, Mick M. EOP/OMB

**Sent:** Wednesday, October 25, 2017 5:29 PM

**To:** Cordish, Reed S. EOP/WHO (b) (6); Collins, Francis (NIH/OD) [E] <(b) (6)>

**Cc:** Grogan, Joseph J. EOP/OMB (b) (6); Georges, Liza B. EOP/WHO (b) (6)

**Subject:** RE:

Count me in. Just let me know when.

-----Original Message-----

From: Cordish, Reed S. EOP/WHO (b) (6)  
Sent: Wednesday, October 25, 2017 4:39 PM  
To: Mulvaney, Mick M. EOP/OMB (b) (6) Collins, Francis  
(NIH/OD) [E] (b) (6)  
Cc: Grogan, Joseph J. EOP/OMB (b) (6); Georges, Liza B.  
EOP/WHO (b) (6)  
Subject:

Now that we are passed the pressure of planning for tomorrow I thought it would make sense to meet and discuss plan of action on opioids. Director Collins has an interesting (b) (5) idea that may resonate well with Administration positioning.

Reed S. Cordish  
Assistant to the President  
White House Office of American Innovation  
(b) (6) (Direct)  
(b) (6)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 26 Oct 2017 19:21:32 +0000  
**To:** Hardesty, Rebecca (NIH/OD) [C]; Hallett, Adrienne (NIH/OD) [E]; McGarey, Barbara (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Johnson, Alfred (NIH/OD) [E]; Godin, Jacquelyn (NIH/OD) [E]  
**Cc:** Burrus-Shaw, Cyndi (NIH/OD) [E]; Casselle, Julia (NIH/OD) [C]; Harris, Melissa (NIH/OD) [E]; Schulke, Hilda (NIH/NIDA) [E]; Walker, Paula (NIH/NINDS) [E]  
**Subject:** Re: OMB meeting for Monday!

Just a reminder that whatever is decided regarding FNIH's role will have to through approval process with our Board of course.

Sent from my BlackBerry 10 smartphone.

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thursday, October 26, 2017 3:12 PM  
**To:** Hardesty, Rebecca (NIH/OD) [C]; Hallett, Adrienne (NIH/OD) [E]; McGarey, Barbara (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Johnson, Alfred (NIH/OD) [E]; Godin, Jacquelyn (NIH/OD) [E]  
**Cc:** Burrus-Shaw, Cyndi (NIH/OD) [E]; Casselle, Julia (NIH/OD) [C]; Harris, Melissa (NIH/OD) [E]; Schulke, Hilda (NIH/NIDA) [E]; Walker, Paula (NIH/NINDS) [E]  
**Subject:** RE: OMB meeting for Monday!

I will not be able to be on the call as (b) (6)

---

**From:** Hardesty, Rebecca (NIH/OD) [C]  
**Sent:** Thursday, October 26, 2017 2:24 PM  
**To:** Hallett, Adrienne (NIH/OD) [E] (b) (6); McGarey, Barbara (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shapiro, Neil (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Godin, Jacquelyn (NIH/OD) [E] (b) (6)  
**Cc:** Burrus-Shaw, Cyndi (NIH/OD) [E] (b) (6); Casselle, Julia (NIH/OD) [C] (b) (6); Harris, Melissa (NIH/OD) [E] (b) (6); Schulke, Hilda (NIH/NIDA) [E] (b) (6); Walker, Paula (NIH/NINDS) [E] (b) (6)  
**Subject:** RE: OMB meeting for Monday!  
**Importance:** High

Hi Everyone,

The meeting is confirmed for 4:30PM today in Building (b) (6) room (b) (6). For those unable to join in person please use the dial-in information below.

Dial-in: (b) (6)

Participant Code: (b) (6)

Materials will be sent out closer to the start time.

Thank you,

Rebecca

---

**From:** Wolinetz, Carrie (NIH/OD) [E]

**Sent:** Thursday, October 26, 2017 1:10 PM

**To:** Hallett, Adrienne (NIH/OD) [E] (b) (6); McGarey, Barbara (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Shapiro, Neil (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Hardesty, Rebecca (NIH/OD) [C] (b) (6); Godin, Jacquelyn (NIH/OD) [E] (b) (6)>

**Subject:** Re: OMB meeting for Monday!

I've asked Rebecca to see if we can pull together a quick meeting/call this afternoon.

Francis, given your commitment this afternoon, we will leave you out of it for now but will return to you shortly with some ideas to noodle upon. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.  
Acting Chief of Staff and  
Associate Director for Science Policy  
Office of the Director  
National Institutes of Health  
(b) (6)

----- Original message -----

From: "Hallett, Adrienne (NIH/OD) [E]" (b) (6)

Date: 10/26/17 1:06 PM (GMT-05:00)

To: "McGarey, Barbara (NIH/OD) [E]" (b) (6), "Collins, Francis (NIH/OD) [E]" (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wolinetz, Carrie (NIH/OD) [E]"



(b) (6), "Shapiro, Neil (NIH/OD) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6), "Volkow, Nora (NIH/NIDA) [E]" (b) (6), "Koroshetz, Walter (NIH/NINDS) [E]" (b) (6), "Stein, Jack (NIH/NIDA) [E]" (b) (6), "Porter, Linda (NIH/NINDS) [E]" (b) (6), "Johnson, Alfred (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>  
Subject: RE: OMB meeting for Monday!

I'm around too.

Just for Barb:

(b) (5)

(b) (5)

---

**From:** McGarey, Barbara (NIH/OD) [E]  
**Sent:** Thursday, October 26, 2017 1:01 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) Shapiro, Neil (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Subject:** RE: OMB meeting for Monday!

Yes – (b) (5)  
(b) (5) I'm around if there is a huddle.

Barb

Barbara M. McGarey, JD  
Deputy Associate General Counsel  
Office of the General Counsel  
Public Health Division, NIH Branch  
31 Center Drive, Rm 2B-50  
Bethesda, MD 20892-2111  
(b) (6) (p)  
(301) 402-1034 (f)  
(b) (6)

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, October 26, 2017 12:28 PM  
**To:** Baker, Rebecca (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shapiro, Neil (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6)

Burklow, John (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; McGarey, Barbara (NIH/OD) [E] (b) (6)

**Subject:** OMB meeting for Monday!

Hi All,

Just saw this meeting has been scheduled for 11 am Monday 10/30. We need to provide pre-read by tomorrow. That will need to include a description of the research needs for opioids and pain (pretty much what we've been saying all along, but did we ever get feedback from ASER?) And then there needs to be an articulation of how the (b) (5) challenge would work. (b) (5)

Thoughts? Please share ASAP. Rebecca, can you start a draft?

FC

Sent from my iPhone

Begin forwarded message:

**From:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Date:** October 25, 2017 at 7:30:03 PM EDT  
**To:** "Grogan, Joseph J. EOP/OMB" (b) (6), "Mulvaney, Mick M. EOP/OMB" (b) (6), "Cordish, Reed S. EOP/WHO" (b) (6)  
**Cc:** "Georges, Liza B. EOP/WHO" (b) (6)  
**Subject:** RE:

Of course. On it.

Francis

-----Original Message-----

**From:** Grogan, Joseph J. EOP/OMB (b) (6)  
**Sent:** Wednesday, October 25, 2017 5:37 PM  
**To:** Mulvaney, Mick M. EOP/OMB (b) (6); Cordish, Reed S. EOP/WHO (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Georges, Liza B. EOP/WHO (b) (6)  
**Subject:** RE:

Yes. And Dr. Collins, if you have any paper on it -- even if rough -- that would be helpful to prepare. Thank you, Joe

-----Original Message-----

From: Mulvaney, Mick M. EOP/OMB

Sent: Wednesday, October 25, 2017 5:29 PM

To: Cordish, Reed S. EOP/WHO (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Grogan, Joseph J. EOP/OMB (b) (6); Georges, Liza B. EOP/WHO (b) (6)

Subject: RE:

Count me in. Just let me know when.

-----Original Message-----

From: Cordish, Reed S. EOP/WHO (b) (6)

Sent: Wednesday, October 25, 2017 4:39 PM

To: Mulvaney, Mick M. EOP/OMB (b) (6); Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Grogan, Joseph J. EOP/OMB (b) (6); Georges, Liza B. EOP/WHO (b) (6)

Subject:

Now that we are passed the pressure of planning for tomorrow I thought it would make sense to meet and discuss plan of action on opioids. Director Collins has an interesting (b) (5) idea that may resonate well with Administration positioning.

Reed S. Cordish

Assistant to the President

White House Office of American Innovation

(b) (6) (Direct)

(b) (6)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 18:28:33 +0000  
**To:** Collins, Francis (NIH/OD) [E]; Chin, Bill  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Re: Opioid Partnership: Co-Chairing the Biomarkers Working Group

I think I am the designated contact and you can refer callers to me.  
Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 12:33 PM  
**To:** Chin, Bill; Wholley, David (FNIH) [T]  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Wow, it seems like a lot of calls are happening to different folks. Do all of us need to get on the phone today and discuss how best to present a single perspective? It seems to me that David ought to be the main point of contact.

FC

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, November 07, 2017 10:29 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Indeed, Chris called. He is concerned about the need to have short-term "fixes" emphasized and while he is (and we are) supporters of biomarkers, he is concerned that the work stream might be viewed as a separate goal independent of the whole. David—In your call, you just need to assure him that all are connected. BTW, others whom you have contacted are also seeking to talk to me. Might we coordinate the discussions a bit? Thanks. Bill

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]  
**Sent:** Tuesday, November 07, 2017 8:40 AM  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Chin, Bill  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

(b) (5)

I just opened his email and will arrange to speak to him today. David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 8:04 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Chin, Bill <Chin@phrma.org>  
**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High



Hi David,

(b) (5)

FC

---

**From:** Flores, Christopher [CONUS] [mailto: (b) (6)]

(b) (6)

**Cc:** Chin, Bill <Chin@phrma.org>

**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group

**Importance:** High

Dear Francis,

As you may be aware, I received yesterday evening the below message from David, which departs in substantial ways from the proposal you sent to Paul Stoffels last week. Notwithstanding whatever role I may play going forward, there exist for me serious concerns regarding the apparent decision to subdivide Focus Area 2. In short, based at least in part on my experience with PPP's as well as my understanding of the present initiative from having participated in multiple steps/meetings leading to this point, I believe this approach has the potential to reduce efficiency and the probability of success.

Moreover, I am concerned about the emphasis here on Project 2c, related to the development of biomarkers, which arguably has very limited potential to address the opioid crisis in the short-term; and I've copied Bill here, as he and I spoke about this last night. Also, after receiving the below message, I immediately offered to have a call with David sometime this week, though I have not yet heard back from him.

Please let me know if you would care to discuss these concerns in greater detail. Otherwise, for the time being, I hope the opportunity still exists to formulate the execution of Focus Area 2 in a way that maximizes the potential of an NIH-PhRMA partnership to have a meaningful effect on accelerating the development of non-addictive/non-opioid analgesics.

Thank you for your consideration,  
Chris

\*\*\*\*\*  
*Christopher M. Flores, Ph.D.*  
*Head, Emerging Science and Innovation Strategy*  
*Johnson & Johnson Consumer Inc.*  
*7050 Camp Hill Road – RA2688*  
*Fort Washington, PA 19034*  
*215.273.8056 (office)*  
*(b) (6) (mobile)*  
*[cflores2@its.jnj.com](mailto:cflores2@its.jnj.com)*  
*[www.linkedin.com/in/chrisfloresinnovator](http://www.linkedin.com/in/chrisfloresinnovator)*

\*\*\*\*\*

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\*\*\*\*\*

*"A society grows great when its elders plant trees in whose shade they know they shall never sit." - Greek Proverb*

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnih.org]  
**Sent:** Monday, November 06, 2017 7:52 PM  
**To:** Flores, Christopher [CONUS] <CFlores2@its.jnj.com>  
**Cc:** Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Baker, Rebecca (NIH/OD) [E] [REDACTED] (b) (6); Thomas, David (NIH/NIDA) [E] [REDACTED] (b) (6); Mark Mintun <mintun@avidrp.com>  
**Subject:** Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

Dear Chris:

Thank you for agreeing to help lead Working Group activities as part of our efforts to develop a public-private partnership to address the national opioid crisis. As you will recall, the partnership has decided to address two focus areas:

1. Develop new formulations and combinations of medications to treat opioid use disorders, and prevent and reverse overdose, and
2. Develop new non-addictive pain therapies-- with Focus Area #2 being further subdivided into three discrete projects: 2a: Share data on successful and failed drug development (with NIH as neutral broker), 2b: Create a clinical trial network to coordinate clinical testing of novel treatments, and 2c: Joint development of biomarkers.

After extensive additional discussion among the sponsors, it has been decided that Nora Volkow's team at NIDA will take the lead in developing ideas for Focus Area 1 and FNIH will lead the design effort for Focus Area 2. **We would like to ask you to please co-chair the Working Group define Project 2c: Joint development of biomarkers (along with Mark Mintun of Lilly and David Thomas of NIDA) as this will no doubt be our most complex challenge.**

Given the urgency of moving forward on this initiative we have agreed on an aggressive timetable for coming up with at least an initial plan for each project that includes several 2-hour phone calls with each Working Group over the next five weeks. **We would therefore ask if you can please work with Cheryl Melencio on our staff to 1) find some times that we can schedule a 30 minute Co-Chair pre-call in the next few days (November 7-10) to agree on an approach and workplan for the Working Group and 2) a list of times that would work best for you to participate in at least the first 2-hour call sometime between the end of next week and the end of the following week (November 10-17).** Please copy Cheryl Melencio and Mike Biarnes on your response. We will set up future calls in parallel with setting up our pre-call discussions with you.

We really look forward to working with you on this important endeavor.

Regards,

David Wholley

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

**(301) 594-6343**

**[fnih.org](http://fnih.org)**

**11400 Rockville Pike Suite 600 North Bethesda, MD 20852**

***Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).***

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 16:27:05 +0000  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Got it. I am speaking to Chris Flores at 2:30 apparently.

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, November 7, 2017 10:54 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

David, I just want to echo your comments. I don't need to be a participant in the calls—in the spirit of speed—but would be eager to hear anything relevant, such as issues that arise, to aid the conversation.  
Bill

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]  
**Sent:** Tuesday, November 07, 2017 10:48 AM  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Yes, Bill I will reassure him. Some of this is normal start-up anxiety I think. How would you suggest we coordinate the discussions? I have my first co-chair precall today (on clinical trials, with Verbarg and Wright) today at 3:30, in keeping with our need to move fast. David

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
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**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

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**Sent:** Tuesday, November 07, 2017 8:40 AM  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Chin, Bill  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

(b) (5)

I just opened his email and will arrange to speak to him today. David

---

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**Sent:** Tuesday, November 7, 2017 8:04 AM



**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Chin, Bill <Chin@phrma.org>  
**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

Hi David,

(b) (5)

FC

---

**From:** Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]  
**Sent:** Tuesday, November 07, 2017 7:47 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Chin, Bill <Chin@phrma.org>  
**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

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Thank you for your consideration,  
Chris

\*\*\*\*\*  
*Christopher M. Flores, Ph.D.*  
*Head, Emerging Science and Innovation Strategy*  
*Johnson & Johnson Consumer Inc.*  
*7050 Camp Hill Road – RA2688*

Fort Washington, PA 19034

215.273.8056 (office)

(b) (6) (mobile)

[cflores2@its.jnj.com](mailto:cflores2@its.jnj.com)

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\*\*\*\*\*  
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\*\*\*\*\*

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**Cc:** Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>; Biarnes, Michael (FNIH) [T]

<[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; Morgan, Emily (FNIH) [T]

<[emorgan@fnih.org](mailto:emorgan@fnih.org)>; Baker, Rebecca (NIH/OD) [E] (b) (6); Thomas, David

(NIH/NIDA) [E] (b) (6); Mark Mintun <[mintun@avidrp.com](mailto:mintun@avidrp.com)>

**Subject:** Opioid Partnership: Co-Chairing the Biomarkers Working Group

**Importance:** High

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We really look forward to working with you on this important endeavor.

Regards,

David Wholley

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fniih.org](http://fniih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: [fniih.org/AnnualReport](http://fniih.org/AnnualReport).*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 15:48:22 +0000  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

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**Sent:** Tuesday, November 7, 2017 10:29 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

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**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

Hi David,

(b) (5)

FC

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**From:** Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]  
**Sent:** Tuesday, November 07, 2017 7:47 AM  
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**Cc:** Chin, Bill <Chin@phrma.org>

**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group

**Importance:** High

Dear Francis,

As you may be aware, I received yesterday evening the below message from David, which departs in substantial ways from the proposal you sent to Paul Stoffels last week. Notwithstanding whatever role I may play going forward, there exist for me serious concerns regarding the apparent decision to subdivide Focus Area 2. In short, based at least in part on my experience with PPP's as well as my understanding of the present initiative from having participated in multiple steps/meetings leading to this point, I believe this approach has the potential to reduce efficiency and the probability of success.

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Thank you for your consideration,  
Chris

\*\*\*\*\*  
Christopher M. Flores, Ph.D.  
Head, Emerging Science and Innovation Strategy  
Johnson & Johnson Consumer Inc.  
7050 Camp Hill Road – RA2688  
Fort Washington, PA 19034  
215.273.8056 (office)  
(b) (6) (mobile)  
[cflores2@its.jnj.com](mailto:cflores2@its.jnj.com)  
[www.linkedin.com/in/chrisfloresinnovator](http://www.linkedin.com/in/chrisfloresinnovator)  
\*\*\*\*\*

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\*\*\*\*\*

*"A society grows great when its elders plant trees in whose shade they know they shall never sit." - Greek Proverb*

---

**From:** Wholley, David (FNIH) [T] (b) (6)  
**Sent:** Monday, November 06, 2017 7:52 PM  
**To:** Flores, Christopher [CONUS] <CFlores2@its.jnj.com>  
**Cc:** Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Morgan, Emily (FNIH) [T] <emorgan@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6) Thomas, David (NIH/NIDA) [E] (b) (6); Mark Mintun <mintun@avidrp.com>  
**Subject:** Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

Dear Chris:

Thank you for agreeing to help lead Working Group activities as part of our efforts to develop a public-private partnership to address the national opioid crisis. As you will recall, the partnership has decided to address two focus areas:

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We really look forward to working with you on this important endeavor.

Regards,

David Wholley

**We've moved! Please find our new address below.**

David Wholley

Director, Research Partnerships

Foundation for the National Institutes of Health

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 13:40:26 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Chin, Bill  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

(b) (5)

I just opened his email and will arrange to speak to him today. David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 8:04 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Chin, Bill <Chin@phrma.org>  
**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
**Importance:** High

Hi David,

(b) (5)

FC

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**From:** Flores, Christopher [CONUS] [mailto:CFlores2@its.jnj.com]  
**Sent:** Tuesday, November 07, 2017 7:47 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Chin, Bill <Chin@phrma.org>  
**Subject:** FW: Opioid Partnership: Co-Chairing the Biomarkers Working Group  
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**Sent:** Monday, November 06, 2017 7:52 PM  
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**Cc:** Melencio, Cheryl (FNIH) [T] <[cmelencio@fnih.org](mailto:cmelencio@fnih.org)>; Biarnes, Michael (FNIH) [T] <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>; Morgan, Emily (FNIH) [T] <[emorgan@fnih.org](mailto:emorgan@fnih.org)>; Baker, Rebecca (NIH/OD) [E] (b) (6); Thomas, David (NIH/NIDA) [E] (b) (6); Mark Mintun <[mintun@avidrp.com](mailto:mintun@avidrp.com)>  
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**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Nov 2017 19:22:31 +0000  
**To:** Chin, Bill; Collins, Francis (NIH/OD) [E]  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

If it is about the pain stuff I am fine with calling people back. I suspect that if it is Focus Area 1 NIH will want that to go to Nora Volkow or perhaps Jack Stein, but that is their decision.

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, November 7, 2017 1:39 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E]  
(b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

That's fine. However, the callers are often not the designated co-chairs, and want to chat in part because they feel they're in the dark. What about questions regarding MAT, repurposing, etc? Bill

---

**From:** Wholley, David (FNIH) [T] [mailto:dwholley@fnihi.org]  
**Sent:** Tuesday, November 07, 2017 1:29 PM  
**To:** Collins, Francis (NIH/OD) [E]; Chin, Bill  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Re: Opioid Partnership: Co-Chairing the Biomarkers Working Group

I think I am the designated contact and you can refer callers to me.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, November 7, 2017 12:33 PM  
**To:** Chin, Bill; Wholley, David (FNIH) [T]  
**Cc:** Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Wow, it seems like a lot of calls are happening to different folks. Do all of us need to get on the phone today and discuss how best to present a single perspective? It seems to me that David ought to be the main point of contact.

FC

---

**From:** Chin, Bill [mailto:Chin@phrma.org]  
**Sent:** Tuesday, November 07, 2017 10:29 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

Indeed, Chris called. He is concerned about the need to have short-term “fixes” emphasized and while he is (and we are) supporters of biomarkers, he is concerned that the work stream might be viewed as a separate goal independent of the whole. David—In your call, you just need to assure him that all are connected. BTW, others whom you have contacted are also seeking to talk to me. Might we coordinate the discussions a bit? Thanks. Bill

---

**From:** Wholley, David (FNIH) [T] [<mailto:dwholley@fnihi.org>]  
**Sent:** Tuesday, November 07, 2017 8:40 AM  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Chin, Bill  
**Subject:** RE: Opioid Partnership: Co-Chairing the Biomarkers Working Group

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(b) (5)

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Regards,

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 23 Oct 2017 18:25:00 +0000  
**To:** Chin, Bill  
**Cc:** Barese, Eric (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; SRAtemp; Dolinski, Kristin; Vereshchagina, Lucy; Moscicki, Richard  
**Subject:** Re: Opioid PPP Planning

By copy to Eric, in process. Thank you, Bill!  
Sent from my BlackBerry 10 smartphone.

---

**From:** Chin, Bill  
**Sent:** Monday, October 23, 2017 1:09 PM  
**To:** Wholley, David (FNIH) [T]  
**Cc:** Barese, Eric (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; SRAtemp; Dolinski, Kristin; Vereshchagina, Lucy; Moscicki, Richard  
**Subject:** Opioid PPP Planning

David, We are prepared to provide the second tranche of the discussed \$200K support to the FNIH of the planning process for the proposed opioid PPP. Can you ask Eric to provide another LOA for the amount of \$100K to begin the process? Thanks. Bill

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 20 Dec 2017 02:45:13 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Collins, Francis (NIH/OD) [E]  
**Subject:** RE: Opioid PPP update for BMAC 12-19-17 draft for NIH

Ok, thanks

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Tuesday, December 19, 2017 9:44 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Collins, Francis (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** Re: Opioid PPP update for BMAC 12-19-17 draft for NIH

Thanks David,

Reading through this now, and will write back soon with thoughts on best strategy for sharing with the rest of the team.

Thanks  
Rebecca

Sent from my iPhone

On Dec 19, 2017, at 7:37 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Francis – Please see my draft of the summary of our progress on the opioid initiative that Bill Chin requested in advance of the January 4 BMAC meeting. He asked for two pages; however given his introductory and closing sections are a page long in themselves my draft result is three pages, but does let them know we've come up with specific conclusions. Feel free to suggest changes to shorten it further of course. I have yet to add the page summarizing AMP and PACT that he requested as this took most of the effort.

(b) (4)

Rebecca, I leave to you whether you think we should simply distribute this more broadly at this point (to Nora, Jack, Walter, etc) or whether you think Francis will want to/have time to make changes first. Bill asked for a final draft by cob tomorrow.

Thanks, David  
<Opioid PPP update for BMAC 12-19-17 draft for NIH.docx>

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 20 Dec 2017 03:22:42 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** RE: Opioid PPP update for BMAC 12-19-17 draft for NIH

By the way, final header in the doc will read BMAC update, not (generic) "Board" Update...

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, December 19, 2017 7:38 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
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Thanks, David



**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 21 Dec 2017 13:12:54 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Subject:** RE: Opioid PPP update for BMAC 12-19-17 integrated clean

Thanks, everyone!

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, December 21, 2017 7:25 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] <rebecca.baker@nih.gov>; Volkow, Nora (NIH/NIDA) [E]  
(b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** RE: Opioid PPP update for BMAC 12-19-17 integrated clean

Looks good to me, fine to send to PhRMA now.

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wednesday, December 20, 2017 7:08 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E]  
(b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Subject:** Opioid PPP update for BMAC 12-19-17 integrated clean

Francis, please see the attached clean final draft of the opioids section of the update on FNIH partnerships requested by the BMAC. It has been reviewed by Larry, Nora, Walter, and Rebecca and I think captures the gist of our meeting and decision process to date. Please let me know any recommended changes as soon as possible so I can send to PhRMA. Thanks, David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Nov 2017 03:23:13 +0000  
**To:** Volkow, Nora (NIH/NIDA) [E]  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

Thanks, Nora!

---

**From:** Volkow, Nora (NIH/NIDA) [E]  
**Sent:** Tuesday, November 28, 2017 10:18 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** Re: Opioids Face-to-Face Meeting Invitation

David. (b) (5) Nora

Sent from my iPhone

On Nov 28, 2017, at 8:10 PM, Wholley, David (FNIH) [T] <dwholley@fnih.org> wrote:

Hi Walter.

(b) (5)

Thanks for the feedback. David

Sent from my BlackBerry 10 smartphone.

---

**From:** Koroshetz, Walter (NIH/NINDS) [E]  
**Sent:** Tuesday, November 28, 2017 7:03 PM  
**To:** Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie

(NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

Thanks David.

(b) (5)

Walter

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, November 28, 2017 4:08 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6) Tabak, Lawrence (NIH/OD) [E]  
(b) (6) Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter  
(NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter,  
Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]  
(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Cc:** Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>  
**Subject:** Opioids Face-to-Face Meeting Invitation

Dear All –

This is regarding the December 12-13 face to face. Can you please see below and let us know asap:

(b) (5)

We really need your feedback asap, preferably this evening (we can send out additional invitations a bit later if needed of course). Please copy Mike Biarnes on your replies.

Thanks, David

---

**From:** Biarnes, Michael (FNIH) [T]  
**Sent:** Monday, November 27, 2017 1:42 PM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>  
**Cc:** Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>  
**Subject:** Opioids Face-to-Face Meeting Information



Hi David,

As discussed, we are working to send out the face-to-face meeting registration information to all members of Focus Area 1 and 2 today or tomorrow. In order to do so, a few items need to be finalized for the registration website:

- Title of the Partnership - [REDACTED] (b) (5)
- Meeting Overview (*Suggested language below*)
- Invitation list (*compiled FA 1 and FA 2 list attached*)

Please let me know your thoughts so that we can finalize these items and get the registration information sent out to all of the working group members.

Thanks,  
Mike

(b) (5)

**We've moved! Please find our new address below.**

**Michael Biarnes**

Scientific Project Manager

**Foundation for the National Institutes of Health**

(301) 594-2612

[fnih.org](http://fnih.org)

**11400 Rockville Pike Suite 600 North Bethesda, MD 20852**

*The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Nov 2017 02:10:18 +0000  
**To:** Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
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Hi Walter.

(b) (5)

Thanks for the feedback. David  
Sent from my BlackBerry 10 smartphone.

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**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
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Thanks David.

(b) (5)

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**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] <rebecca.baker@nih.gov>

**Cc:** Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** Opioids Face-to-Face Meeting Invitation

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**Cc:** Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
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(b) (5)

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Nov 2017 03:26:03 +0000  
**To:** Baker, Rebecca (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

Thanks. Will wait until mid-morning tomorrow (11 am) and unless we hear any feedback to the contrary, Mike please go ahead and pull the trigger on the meeting invitation system. We are working on a preliminary agenda as well...

---

**From:** Baker, Rebecca (NIH/OD) [E]  
**Sent:** Tuesday, November 28, 2017 10:24 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>; Volkow, Nora (NIH/NIDA) [E]  
(b) (6)  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]  
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

I agree with the new language for the biomarkers goal and that "address the opioid crisis" is good. This title is also consistent with what we've used in previous materials.

Best,  
Rebecca

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tuesday, November 28, 2017 10:23 PM  
**To:** Volkow, Nora (NIH/NIDA) [E] (b) (6)  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>; Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

Thanks, Nora!

---

**From:** Volkow, Nora (NIH/NIDA) [E]  
**Sent:** Tuesday, November 28, 2017 10:18 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Collins, Francis (NIH/OD) [E]

(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6) Biarnes, Michael (FNIH) [T] <[mbiarnes@fnihi.org](mailto:mbiarnes@fnihi.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnihi.org](mailto:jmenetski@fnihi.org)>  
**Subject:** Re: Opioids Face-to-Face Meeting Invitation

David. (b) (5) Nora

Sent from my iPhone

On Nov 28, 2017, at 8:10 PM, Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)> wrote:

Hi Walter.

(b) (5)

Thanks for the feedback. David

Sent from my BlackBerry 10 smartphone.

---

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**To:** Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]  
**Cc:** Biarnes, Michael (FNIH) [T]; Menetski, Joseph (FNIH) [T]  
**Subject:** RE: Opioids Face-to-Face Meeting Invitation

Thanks David.

(b) (5)

Walter



---

**From:** Wholley, David (FNIH) [T]

**Sent:** Tuesday, November 28, 2017 4:08 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E]

(b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]

(b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6)

**Cc:** Biarnes, Michael (FNIH) [T] <[mbiarnes@fnih.org](mailto:mbiarnes@fnih.org)>; Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>

**Subject:** Opioids Face-to-Face Meeting Invitation

Dear All –

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(b) (5)

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Thanks, David

---

**From:** Biarnes, Michael (FNIH) [T]

**Sent:** Monday, November 27, 2017 1:42 PM

**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>

**Cc:** Menetski, Joseph (FNIH) [T] <[jmenetski@fnih.org](mailto:jmenetski@fnih.org)>

**Subject:** Opioids Face-to-Face Meeting Information

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- Invitation list (*compiled FA 1 and FA 2 list attached*)

Please let me know your thoughts so that we can finalize these items and get the registration information sent out to all of the working group members.

Thanks,  
Mike

(b) (5)



**We've moved! Please find our new address below.**

**Michael Biarnes**

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**Foundation for the National Institutes of Health**

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**11400 Rockville Pike Suite 600 North Bethesda, MD 20852**

*The FNIH is the #1 ranked biomedical research charitable organization & earned a 4-star rating from Charity Navigator.*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 10 Oct 2017 16:32:25 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** Re: Opioids partnership next steps

Sure.

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, October 10, 2017 12:26 PM  
**To:** Wholley, David (FNIH) [T]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Biarnes, Michael (FNIH) [T]  
**Subject:** RE: Opioids partnership next steps

Hi David,

(b) (5)

Thanks, Francis

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, October 06, 2017 6:24 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Biarnes, Michael (FNIH) [T] <mbiarnes@fnih.org>  
**Subject:** Opioids partnership next steps

Francis, as requested:

Opioid PPP – Next Steps 10/5/17

(b) (4), (b) (5)



**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 2 Oct 2017 21:59:12 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Schwetz, Tara (NIH/OD) [E]  
**Subject:** RE: opioids PPP and where we go next

Hi Francis,  
Yes I did hear, and like everyone am deeply shocked and saddened to hear the reason behind this delay.

Before I answer, let me please make sure that my basic assumptions are correct:

(b) (5)

(b) (5)

Assuming that is true (please tell me right away if I don't have it right),

(b) (5)

(b) (5)

I am happy to discuss of course at any time, including on our Thursday call. Please let me know when you think you have a complete enough list of names to begin.

David

David Wholley

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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, October 02, 2017 12:42 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]  
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora  
(NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6) Porter, Linda  
(NIH/NINDS) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)  
**Subject:** opioids PPP and where we go next

Hi David,

I guess you have heard that the White House event on opioids, tentatively planned for this coming Wednesday, has been postponed due to the POTUS's travel to Las Vegas. But the WH hasn't given up on this. Reed Cordish just called to suggest the idea of an event in about a month – to highlight NIH, FDA, and industry working together on the PPP.

More than two dozen companies have sent in names of designated hitters to serve on the groups that will be charged with putting together a workplan, timetable, and budget for projects #1 and #2. (b) (5)

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 3 Oct 2017 13:49:12 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Volkow, Nora (NIH/NIDA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Stein, Jack (NIH/NIDA) [E]; Porter, Linda (NIH/NINDS) [E]; Schwetz, Tara (NIH/OD) [E]  
**Subject:** RE: opioids PPP and where we go next

Thanks for asking, Francis.

(b) (5)

David

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---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, October 02, 2017 9:35 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)  
**Subject:** RE: opioids PPP and where we go next

Hi David,

I think you have the plan correctly and realistically scoped – I'm asking Nora and Walter to weigh in if they think otherwise.

What you propose for a one month time frame sounds appropriate to me, and (b) (5)

(b) (5)

FC

---

**From:** Wholley, David (FNIH) [T]

**Sent:** Monday, October 02, 2017 5:59 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora (NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda (NIH/NINDS) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)

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(b) (5)

(b) (5)

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(b) (5)

(b) (5)



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**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E]  
(b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Volkow, Nora  
(NIH/NIDA) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E]  
(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Porter, Linda  
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Hi David,

I guess you have heard that the White House event on opioids, tentatively planned for this coming Wednesday, has been postponed due to the POTUS's travel to Las Vegas. But the WH hasn't given up on this. Reed Cordish just called to suggest the idea of an event in about a month – to highlight NIH, FDA, and industry working together on the PPP.

More than two dozen companies have sent in names of designated hitters to serve on the groups that will be charged with putting together a workplan, timetable, and budget for projects #1 and #2. (b) (5)

FC

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 17 Jan 2017 10:37:27 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: PACT

Hi Francis,

(b) (6)

(b) (4)

I guess we'll have to see how things proceed—agree we will of course continue to support NIH and work together in good faith, as always.

Sure hope the signals from that tower are positive.

David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Monday, January 16, 2017 12:46 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** PACT

Hi David,

(b) (6)

(b) (5)

(b) (5)

Best, Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 24 Jan 2017 08:49:58 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]  
**Subject:** RE: PACT and (b) (4)

That's great, Francis—I will get Cheryl working with your office on the first meeting, would like to do this as soon as possible as we have some issues to address. I would like to propose at least 45 minutes for the first meeting if you can spare the time.

(b) (4)

David

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Tuesday, January 24, 2017 7:17 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** PACT and (b) (4)

Hi David,

I'm back from (b) (6) and it seems I am still NIH Director — (b) (5)

I'm glad to say that PACT was well received in the meetings I had with industry.

(b) (4)

(b) (4)

I think we are at a critical juncture with PACT, and now that my tenure at NIH has been extended, I'd like to set up monthly briefings from you and Stacey about progress.

(b) (5)

(b) (5)

(b) (5)

(b) (5) We should not be shy to follow up with him when we have a specific proposal to make.

Best, Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 5 Mar 2017 17:59:56 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: PACT and PhRMA

Thanks for responding so quickly, Francis.

(b) (5)

(b) (5)

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, March 05, 2017 3:38 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT and PhRMA

Hi David,

(b) (4)

(b) (5)

FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, March 03, 2017 5:12 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** PACT and PhRMA

Francis:

(b) (4)

(b) (4)

(b) (4)

Do you see any problem with this? I wanted to get your view first before I pose the same question to Doug and Jim. I promised Bill I'd get back to him shortly, so he can begin his internal deliberations.

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Tue, 7 Mar 2017 10:57:40 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: PACT and PhRMA

FYI, just heard from Jim Doroshow, and he is fine with Bill participating as discussed. I will follow up with Bill.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, March 05, 2017 6:45 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT and PhRMA

That all sounds good, thanks.

FC

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sunday, March 05, 2017 6:00 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT and PhRMA

Thanks for responding so quickly, Francis.

(b) (5)

(b) (5)

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, March 05, 2017 3:38 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT and PhRMA

Hi David,

(b) (4)

(b) (4)



FC

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**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, March 03, 2017 5:12 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** PACT and PhRMA

Francis:

(b) (4)

(b) (4) Do you see any problem with this? I wanted to get your view first before I pose the same question to Doug and Jim. I promised Bill I'd get back to him shortly, so he can begin his internal deliberations.

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 9 Apr 2017 16:20:11 -0400  
**To:** Collins, Francis (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshov, James (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]  
**Subject:** Re: PACT at Hever

Thanks for this thorough summary, Francis. With few exceptions it sounds like in the end this went the way we'd kind of expected it to go.

David

Sent from my BlackBerry 10 smartphone.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 9, 2017 3:49 PM  
**To:** Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Lowy, Douglas (NIH/NCI) [E]; Doroshov, James (NIH/NCI) [E]; Tabak, Lawrence (NIH/OD) [E]  
**Cc:** Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]  
**Subject:** PACT at Hever

Hi all,

The Cancer Moonshot and PACT were discussed for 90 minutes this morning at Hever. See attached for the ppt deck that was presented. Jim Doroshov did a great job of walking the pharma R&D chiefs through the Blue Ribbon Panel process, and outlining the areas of focus for FY17. He also described some of NCI's investments in immunotherapy trials and biomarkers, and the status of the Virtual Formulary. Then I led them through the current plans for PACT. I mentioned that multiple discussions were going on with potential participant companies – and that by my count so far, 5/17 were distinctly positive, 9/17 were in the deliberative process, and only 3/17 indicated they would probably not join.

The discussion format was a little odd – in that there was a discussant (Morten Sogaard of Pfizer) inserted at the end (slides 24 – 27), with perspectives that were reportedly derived from a Hever phone call prior to the meeting, but seem particularly to reflect the views of Dolsten. I don't mean to sound overly negative about this framing, however, as I don't think it had a major influence on the discussion that followed.

Here are some of the points that surfaced:



Jim, please add other information from your vantage point, or correct any misstatements I have made.

Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 10 Apr 2017 21:13:12 -0400  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: PACT at Hever

Hi Francis--My take on this is that we don't need to anything specific to respond here (you and Jim seem to have done a pretty great job of that) other than keep pushing to get replies by June and maybe connect with Paul about IMI2. Is that your sense?

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Sunday, April 09, 2017 3:50 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; Lowy, Douglas (NIH/NCI) [E] (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)  
**Cc:** Baker, Rebecca (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)  
**Subject:** PACT at Hever

Hi all,

The Cancer Moonshot and PACT were discussed for 90 minutes this morning at Hever. See attached for the ppt deck that was presented. Jim Doroshov did a great job of walking the pharma R&D chiefs through the Blue Ribbon Panel process, and outlining the areas of focus for FY17. He also described some of NCI's investments in immunotherapy trials and biomarkers, and the status of the Virtual Formulary. Then I led them through the current plans for PACT. I mentioned that multiple discussions were going on with potential participant companies – and that by my count so far, 5/17 were distinctly positive, 9/17 were in the deliberative process, and only 3/17 indicated they would probably not join.

The discussion format was a little odd – in that there was a discussant (Morten Sogaard of Pfizer) inserted at the end (slides 24 – 27), with perspectives that were reportedly derived from a Hever phone call prior to the meeting, but seem particularly to reflect the views of Dolsten. I don't mean to sound overly negative about this framing, however, as I don't think it had a major influence on the discussion that followed.

Here are some of the points that surfaced:

(b) (5)



Jim, please add other information from your vantage point, or correct any misstatements I have made.

Francis

**From:** Wholley, David (FNIH) [T]  
**Sent:** Wed, 29 Mar 2017 20:01:59 -0400  
**To:** Lowy, Douglas (NIH/NCI) [E]; Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Re: PACT discussion with (b) (4), (b) (6)

Thanks Doug. I think I conveyed something along these lines.  
Sent from my BlackBerry 10 smartphone.

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Wednesday, March 29, 2017 5:52 PM  
**To:** Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]  
**Cc:** Adam, Stacey (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]  
**Subject:** Re: PACT discussion with (b) (4), (b) (6)

Hi David,

Many thanks for your efforts and update. Tom's concerns are understandable and reasonable.

(b) (5)

(b) (7)

Doug

---

**From:** "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>  
**Date:** Wednesday, March 29, 2017 at 5:01 PM  
**To:** "Collins, Francis (NIH/OD) [E]" (b) (6) "Doroshow, James (NIH/NCI) [E]" (b) (6), "Lowy, Douglas" (b) (6)  
**Cc:** "Adam, Stacey (FNIH) [T]" <sadam@fnihi.org>, "Baker, Rebecca (NIH/OD) [E]" (b) (6)  
**Subject:** PACT discussion with (b) (4), (b) (6)

Hi Francis, Doug, and Jim:

I just want to let you know we had a pretty promising discussion about PACT this afternoon with (b) (4), (b) (4), (b) (6), and Vicki Goodman, who served on the PACT Working Group.

(b) (4)

(b) (4)  
(b) (4)

(b) (5)

Thanks,  
David

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 6 Nov 2017 14:03:31 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Subject:** RE: PACT EC

Francis, will do, and I will let Jim know you are starting out as co-chair. FYI I would imagine EC would not meet before early December—we'll need that long to come up with a final research plan that the delegates to the F2F agree to, not to mention electing the company reps. I assume the rest of the structure as I have described it suits you.

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Saturday, November 4, 2017 4:04 PM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** FW: PACT EC

Hi David,

See below.

(b) (5)

(b) (5)

FC

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**From:** Tabak, Lawrence (NIH/OD) [E]  
**Sent:** Friday, November 03, 2017 1:01 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Subject:** Re: PACT EC

We would need to discuss with Gretchen.

(b) (5)

(b) (5)

---

**From:** Francis Collins (b) (6)  
**Date:** Friday, November 3, 2017 at 12:58 PM  
**To:** "Tabak, Lawrence (NIH/OD) [E]" (b) (6)  
**Subject:** FW: PACT EC

See below.

(b) (5)

---

**From:** Wholley, David (FNIH) [T]  
**Sent:** Friday, November 03, 2017 11:50 AM



**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Subject:** PACT EC

Hi Francis –

Back to PACT for a moment. Stacey Adam and I met with Jim Doroshow and his NCI team last night to start getting set for the face to face meeting we are holding on November 16 to finalize the detailed research plan for PACT (as we did with the AMP initiatives). Among the topics tackled was governance, and NCI is working on suggested representatives for the JSC.

(b) (5)

Thanks, David

**We've moved! Please find our new address below.**

**David Wholley**

**Director, Research Partnerships**

**Foundation for the National Institutes of Health**

(301) 594-6343

[fnih.org](http://fnih.org)

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*Learn more about the FNIH in our **2016 Annual Report**: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

**From:** Wholley, David (FNIH) [T]  
**Sent:** Mon, 9 Oct 2017 17:05:47 +0000  
**To:** Myles, Renate (NIH/OD) [E]; Lowy, Douglas (NIH/NCI) [E]; Collins, Francis (NIH/OD) [E]; Lowy, Douglas (NCI)  
**Cc:** Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Doroshow, James (NIH/NCI) [E]; Burklow, John (NIH/OD) [E]; Garrett, Peter (NIH/NCI) [E]; Lubenow, Anne (NIH/NCI) [E]; Adam, Stacey (FNIH) [T]; Hallett, Adrienne (NIH/OD) [E]; Berkson, Laura (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; Vitelli, Cynthia (NIH/NCI) [E]; Hatch, Shannon (NIH/NCI) [E]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]  
**Subject:** RE: PACT Rollout Plan

I know she will not be acting as the patient representative, but should we not invite Ellen Sigal to attend? Stacey and I have briefed her several times on PACT (she is on the FNIH Board) and I think her support going forward with the cancer community and FDA will be very helpful.

(I am assuming Stacey, Maria, and I will attend from FNIH.)

**David Wholley**  
**Director, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

---

**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Monday, October 09, 2017 12:48 PM  
**To:** Lowy, Douglas (NIH/NCI) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NCI) (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Hallett, Adrienne (NIH/OD) [E] (b) (6); Berkson, Laura (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6); Hatch, Shannon (NIH/NCI) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT Rollout Plan

You mean we're lucky to get to have you! ☺

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Monday, October 09, 2017 12:44 PM

**To:** Myles, Renate (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NCI) (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Adam, Stacey (FNIH) [T] <[sadam@fnihi.org](mailto:sadam@fnihi.org)>; Hallett, Adrienne (NIH/OD) [E] (b) (6); Berkson, Laura (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6); Hatch, Shannon (NIH/NCI) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)  
**Subject:** Re: PACT Rollout Plan

For the moment, you're stuck with me for NCI. I'll let you know if that changes. Doug

---

**From:** "Myles, Renate (NIH/OD) [E]" (b) (6)  
**Date:** Monday, October 9, 2017 at 12:41 PM  
**To:** "Lowy, Douglas" (b) (6), "Collins, Francis (NIH/OD) [E]" (b) (6), "Lowy, Douglas (NCI)" (b) (6)  
**Cc:** "Tabak, Lawrence (NIH/OD) [E]" <[lawrence.tabak@nih.gov](mailto:lawrence.tabak@nih.gov)>, "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Doroshow, James (NIH/NCI) [E]" (b) (6), "Burklow, John (NIH/OD) [E]" (b) (6), "Garrett, Peter (NIH/NCI) [E]" (b) (6), "Lubenow, Anne (NIH/NCI) [E]" (b) (6), "Wholley, David (FNIH) [T]" <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>, "Adam, Stacey (FNIH) [T]" <[sadam@fnihi.org](mailto:sadam@fnihi.org)>, "Hallett, Adrienne (NIH/OD) [E]" (b) (6), "Berkson, Laura (NIH/OD) [E]" (b) (6), "Wojtowicz, Emma (NIH/OD) [E]" (b) (6), "Vitelli, Cynthia (NIH/NCI) [E]" (b) (6), "Hatch, Shannon (NIH/NCI) [E]" (b) (6), "Wood, Gretchen (NIH/OD) [E]" (b) (6), "McManus, Ayanna (NIH/OD) [E]" (b) (6)  
**Subject:** RE: PACT Rollout Plan

Thanks for letting me know that Jim won't be there. Will there be other principals from NCI who will be attending who I should add to the list? And thanks for the catch of the typo on Maria's name.

---

**From:** Lowy, Douglas (NIH/NCI) [E]  
**Sent:** Monday, October 09, 2017 12:39 PM  
**To:** Myles, Renate (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Lowy, Douglas (NCI) (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Doroshow, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <[dwholley@fnihi.org](mailto:dwholley@fnihi.org)>; Adam, Stacey (FNIH) [T] <[sadam@fnihi.org](mailto:sadam@fnihi.org)>; Hallett, Adrienne (NIH/OD) [E] (b) (6); Berkson, Laura



(NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6) Hatch, Shannon (NIH/NCI) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)

**Subject:** Re: PACT Rollout Plan

Thanks, Renate. 1) Placing me between the industry representative and Melinda is fine with me. 2) I would like to clarify that Jim Doroshow will not be there, as he had a long-standing commitment in the UK. 3) Dr. Freire's first name is Maria, rather than Marie. Doug

---

**From:** "Myles, Renate (NIH/OD) [E]" (b) (6)  
**Date:** Monday, October 9, 2017 at 12:20 PM  
**To:** "Collins, Francis (NIH/OD) [E]" (b) (6), "Lowy, Douglas (NCI)" (b) (6)  
**Cc:** "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wolinetz, Carrie (NIH/OD) [E]" (b) (6), "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Doroshow, James (NIH/NCI) [E]" (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6), "Garrett, Peter (NIH/NCI) [E]" (b) (6) "Lubenow, Anne (NIH/NCI) [E]" (b) (6) "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Adam, Stacey (FNIH) [T]" <sadam@fnih.org>, "Hallett, Adrienne (NIH/OD) [E]" (b) (6), "Berkson, Laura (NIH/OD) [E]" (b) (6) "Wojtowicz, Emma (NIH/OD) [E]" (b) (6) "Vitelli, Cynthia (NIH/NCI) [E]" (b) (6), "Hatch, Shannon (NIH/NCI) [E]" (b) (6), "Wood, Gretchen (NIH/OD) [E]" (b) (6) "McManus, Ayanna (NIH/OD) [E]" (b) (6)  
**Subject:** RE: PACT Rollout Plan

Hi Francis and Doug:

Attached are the event details, including a proposed agenda. We thought it made sense if the Acting Secretary went first so he could leave after his remarks, if he so wishes. We also thought that the industry representative should go before Doug so that Doug can talk about the CIMACs and the CIDC and how these will support PACT efforts. We also thought it made more sense for Doug to introduce Melinda rather than have an industry person do that. Let me know if you agree.

The release is in HHS clearance and has also been shared with all of the partner organizations for a partner quotes and bios. We are still waiting to hear from partner organizations on their participation in the event. Currently, only GSK, Pfizer and Janssen have confirmed participation. We expect to hear from Dr. Tom Hudson of AbbVie today on whether he is able to speak on behalf of industry partners. BMS and Celgene declined and did not offer a substitute. We will keep you posted as this develops.

Best,  
Renate

---

**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, October 05, 2017 8:25 PM

**To:** Myles, Renate (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Lowy, Douglas (NCI) (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; Hallett, Adrienne (NIH/OD) [E] (b) (6); Berkson, Laura (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6); Hatch, Shannon (NIH/NCI) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)  
**Subject:** RE: PACT Rollout Plan

Looks good. But we need to clarify the run of show for the actual event. Acting Secy Don Wright sounded willing when I spoke to him last Tuesday, but I don't think that's been put on his calendar yet. And rumor has it that we might have a new Acting Secy (Eric Hargan) by next week.

We had discussed having Sandra Horning (Roche/Genentech) as the industry speaker. Have we heard from her about whether she's planning to come?

FC

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**From:** Myles, Renate (NIH/OD) [E]  
**Sent:** Thursday, October 05, 2017 10:36 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Wolinetz, Carrie (NIH/OD) [E] (b) (6); Baker, Rebecca (NIH/OD) [E] (b) (6); Lowy, Douglas (NCI) (b) (6); Doroshov, James (NIH/NCI) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6); Garrett, Peter (NIH/NCI) [E] (b) (6); Lubenow, Anne (NIH/NCI) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Adam, Stacey (FNIH) [T] <sadam@fnihi.org>; Hallett, Adrienne (NIH/OD) [E] (b) (6); Berkson, Laura (NIH/OD) [E] (b) (6); Wojtowicz, Emma (NIH/OD) [E] (b) (6); Vitelli, Cynthia (NIH/NCI) [E] (b) (6); Hatch, Shannon (NIH/NCI) [E] (b) (6); Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6)>  
**Subject:** PACT Rollout Plan

Good morning, Francis:

Attached is the PACT rollout plan. The release and media availability were sent to FNIH this morning for review and we hope to have them to you this afternoon for final review, after NCI coordinates review by Doug and Jim. I will be out of the office today and tomorrow, so Emma will keep things moving.

Best,  
Renate

**From:** Wholley, David (FNIH) [T]  
**Sent:** Thu, 5 Oct 2017 14:51:31 +0000  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Adam, Stacey (FNIH) [T]  
**Subject:** RE: PACT

Yeahh!

David Wholley  
Director, Research Partnerships  
Foundation for the National Institutes of Health  
(301) 594-6343  
[fnih.org](http://fnih.org)

*Learn more about the FNIH in our 2016 Annual Report: [fnih.org/AnnualReport](http://fnih.org/AnnualReport).*

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**From:** Collins, Francis (NIH/OD) [E]  
**Sent:** Thursday, October 05, 2017 10:45 AM  
**To:** Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** Fwd: PACT

Woo hoo!

Sent from my iPhone

Begin forwarded message:

**From:** "Bradner, James" <[james.bradner@novartis.com](mailto:james.bradner@novartis.com)>  
**Date:** October 5, 2017 at 9:58:48 AM EDT  
**To:** "Collins, Francis (NIH/OD) [E]" (b) (6)  
**Cc:** "Rammohan, Revathi" <[revathi.rammohan@novartis.com](mailto:revathi.rammohan@novartis.com)>, "Brown, Scott" <[scott.brown@novartis.com](mailto:scott.brown@novartis.com)>, "Engelman, Jeffrey" <[jeffrey.engelman@novartis.com](mailto:jeffrey.engelman@novartis.com)>, "Hammerman, Peter" <[peter.hammerman@novartis.com](mailto:peter.hammerman@novartis.com)>, "Dranoff, Glenn" <[glenn.dranoff@novartis.com](mailto:glenn.dranoff@novartis.com)>, "Petruzzelli, Lilli" <[lilli.petruzzelli@novartis.com](mailto:lilli.petruzzelli@novartis.com)>, "Lockwood, Jeffrey" <[jeffrey.lockwood@novartis.com](mailto:jeffrey.lockwood@novartis.com)>  
**Subject:** PACT

francis.

thank you for the invitation to steer and now join the NIH-PACT program focused on cancer immunotherapy biomarker discovery. this week we assembled our cancer and institutional leadership (many cc'd here), to examine the clarified design principles emerging from the workstream and to assess alignment with our critical path in IO and cancer medicine. we applaud the effort to pull together so many leading institutions and scientists around this generational activity. we agree violently that the



development of next-generation IO agents will require new measurements guiding use and explaining (in)activity. in this regard, we are well aligned with the program and would like to participate.

my sense is that there are important strategic details still to define, regarding scientific focus, institutions/scientific leaders involved, clarified and prioritized measurements. jeff, peter, glenn and lilli cc'd will surely have helpful guidance, should the PACT welcome insights at this pivotal stage. candidly, our principal interest remains connected to the safe harbor the PACT might provide for combination clinical trials of next-gen agents between companies. we would welcome a chance to work with peer institutions through the NIH network. but even with a focus on biomarker creation, curation and deployment, we are motivated to join. i defer to jeff to provide guidance as to how best and who best to contribute these and other guidance.

(b) (4)

finally, we are working hard to help you hit your deadline on the announcement and would like to be a party to the announcement. peter can join in DC at the national press club, if this invitation is still open and helpful.

thank you for the invitation, again, to join. we so admire the heroic work you continue to lead, orienting our government around this rarified moment in biomedicine, openly assembling diverse research communities, and always defending basic research.

please advise on next steps.

best - jay

--

**Jay Bradner, M.D.**

President | Novartis Institutes for BioMedical Research

[james.bradner\[at\]novartis.com](mailto:james.bradner@novartis.com)

**From:** Wholley, David (FNIH) [T]  
**Sent:** Sun, 9 Apr 2017 15:16:03 -0400  
**To:** Volkow, Nora (NIH/NIDA) [E]; Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]  
**Cc:** Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Schulke, Hilda (NIH/NIDA) [E]  
**Subject:** Re: Pain PPP -- report from Hever

Yes, I'll be on. If OK I will ask my deputy Joe Menetski to join as well.  
Sent from my BlackBerry 10 smartphone.

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**From:** Volkow, Nora (NIH/NIDA) [E]  
**Sent:** Sunday, April 9, 2017 3:12 PM  
**To:** Collins, Francis (NIH/OD) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Tabak, Lawrence (NIH/OD) [E]; Wholley, David (FNIH) [T]; Baker, Rebecca (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]  
**Cc:** Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Stein, Jack (NIH/NIDA) [E]; Schulke, Hilda (NIH/NIDA) [E]  
**Subject:** Re: Pain PPP -- report from Hever

Standing by. nora

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**From:** Francis Collins (b) (6)  
**Date:** Sunday, April 9, 2017 at 3:10 PM  
**To:** Nora Volkow (b) (6), Walter Koroshetz (b) (6) "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnih.org>, "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Schwetz, Tara (NIH/OD) [E]" (b) (6)  
**Cc:** "Wood, Gretchen (NIH/OD) [E]" (b) (6), "McManus, Ayanna (NIH/OD) [E]" (b) (6), Jack Stein (b) (6), Hilda Schulke (b) (6)  
**Subject:** RE: Pain PPP -- report from Hever

Waiting to hear from Walter and David about a 7 AM call tomorrow. If we can do it, the coordinates are:

Dial: (b) (6) Code: (b) (6)

I'll be leader.

FC

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**From:** Volkow, Nora (NIH/NIDA) [E]  
**Sent:** Sunday, April 09, 2017 3:00 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6) Wholley, David (FNIH) [T] <dwholley@fnih.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)>  
**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E]



(b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6); Schulke, Hilda (NIH/NIDA) [E] (b) (6)

**Subject:** Re: Pain PPP -- report from Hever

What number should we call? I am attaching a relevant paper nora

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**From:** Francis Collins (b) (6) 1/151 | Dial: (b) (6) Code: (b) (6) Leader: (b) (6)  
>

**Date:** Sunday, April 9, 2017 at 2:56 PM

**To:** Nora Volkow (b) (6), Walter Koroshetz (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>, "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Schwetz, Tara (NIH/OD) [E]" (b) (6)

**Cc:** "Wood, Gretchen (NIH/OD) [E]" (b) (6), "McManus, Ayanna (NIH/OD) [E]" (b) (6), Jack Stein (b) (6)

**Subject:** RE: Pain PPP -- report from Hever

Let's try for 7 AM -- does that work for others in the "to" line?

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**From:** Volkow, Nora (NIH/NIDA) [E]

**Sent:** Sunday, April 09, 2017 2:47 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6); Koroshetz, Walter (NIH/NINDS) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6); Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Baker, Rebecca (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)

**Cc:** Wood, Gretchen (NIH/OD) [E] (b) (6); McManus, Ayanna (NIH/OD) [E] (b) (6); Stein, Jack (NIH/NIDA) [E] (b) (6)

**Subject:** Re: Pain PPP -- report from Hever

Francis: I am glad that you were able to get big pharma interested and responsive to the need for accelerating medications in pain and addiction. I fly tomorrow at 8 AM to a meeting in North Carolina and will be back tomorrow night so it will be hard for me to connect at 8AM. However I am available at 6:30 or 7 AM tomorrow or any other time during the week.

(b) (5)  
However I wondered whether its best to have them separated as u suggest to avoid dilution of goals. We are trying to see if we can schedule both meetings in June (if we have 3 then we can plan the basic science one for later). Larry is helping us find a suitable conference room in such a short notice.

Also thanks very much for advancing this initiative nora

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**From:** Francis Collins (b) (6)

**Date:** Sunday, April 9, 2017 at 2:31 PM

**To:** Nora Volkow (b) (6), Walter Koroshetz (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Wholley, David (FNIH) [T]" <dwholley@fnihi.org>, "Baker, Rebecca (NIH/OD) [E]" (b) (6), "Schwetz, Tara (NIH/OD) [E]" (b) (6)

**Cc:** "Wood, Gretchen (NIH/OD) [E]" (b) (6), "McManus, Ayanna (NIH/OD) [E]" (b) (6)

**Subject:** Pain PPP -- report from Hever

Hi all,

(b) (6), and am glad to give you a generally positive report about the Hever discussions on a PPP on the opioid crisis. It took two tries – the first discussion yesterday was a bit chaotic and ran up against a time crunch with the rest of the Hever agenda. With support from the Chair, I negotiated for a second session this morning (asking members to come early). That went much better. Attached are the ppt files used for each session. For the first ppt file, the Pain proposal begins at slide 12. The second one was created last night.

Here are the high points:

(b) (5)

